US008979822B2

(12) **United States Patent**
Vogelbaum et al.

(10) **Patent No.: US 8,979,822 B2**
(45) **Date of Patent: *Mar. 17, 2015**

(54) **CATHETER ASSEMBLY**

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(73) Assignee: **The Cleveland Clinic Foundation**, Cleveland, OH (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 48 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/487,395**

(22) Filed: **Jun. 4, 2012**

(65) **Prior Publication Data**

US 2012/0323175 A1 Dec. 20, 2012

Related U.S. Application Data

(60) Provisional application No. 61/493,777, filed on Jun. 6, 2011.

(51) **Int. Cl.**

A61M 25/00	(2006.01)
A61M 25/01	(2006.01)
A61M 25/10	(2013.01)

(52) **U.S. Cl.**

CPC ***A61M 25/0102*** (2013.01); ***A61M 25/0054*** (2013.01); ***A61M 25/003*** (2013.01); ***A61M 25/0082*** (2013.01); ***A61M 25/1002*** (2013.01); *A61M 2025/0024* (2013.01); *A61M 2025/0039* (2013.01); *A61M 2025/0057* (2013.01);
(Continued)

(58) **Field of Classification Search**

CPC A61M 25/0067; A61M 25/0074; A61M 25/0082; A61M 25/0084; A61M 25/0087; A61M 25/0054; A61M 25/0063
USPC 604/264, 95.04, 525
See application file for complete search history.

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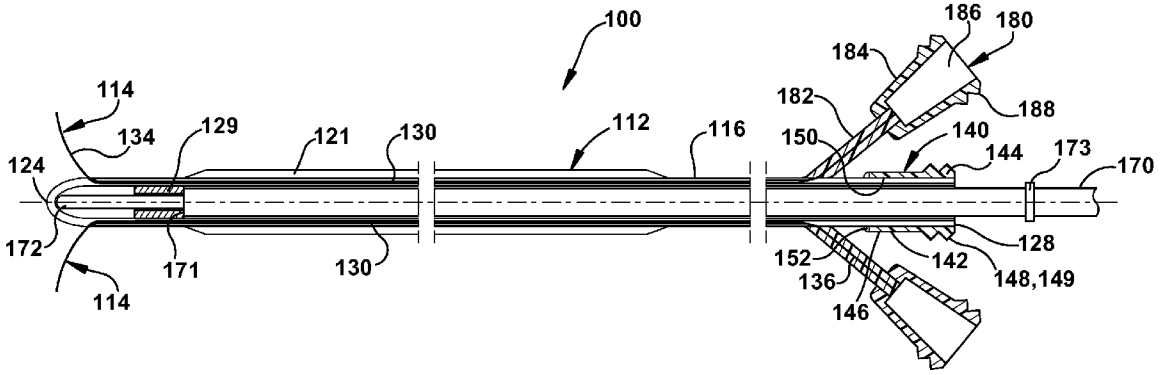
Primary Examiner — Laura Bouchelle
(74) *Attorney, Agent, or Firm* — Tarolli, Sundheim, Covell & Tummino LLP

(57) **ABSTRACT**

A catheter assembly comprises a first catheter including a wall with an inner surface at least partially defining a lumen. A second catheter is connected to the wall of the first catheter and is disposed outward of the inner surface of the wall. The second catheter is at least partially covered by a sheath portion of the first catheter. A first portion of the wall of the first catheter is made of a relatively low durometer elastomeric material and is relatively extensible. A second portion of the wall is formed of a relatively high durometer elastomeric material and is relatively inextensible.

81 Claims, 14 Drawing Sheets



(52) **U.S. Cl.**
CPC *A61M2025/0096* (2013.01); *A61M 2025/0175* (2013.01); *A61M 2025/105* (2013.01); *A61M 2025/1086* (2013.01); *A61M 2025/1093* (2013.01); *A61M 2210/0693* (2013.01)
USPC **604/525**; 604/528; 604/95.04

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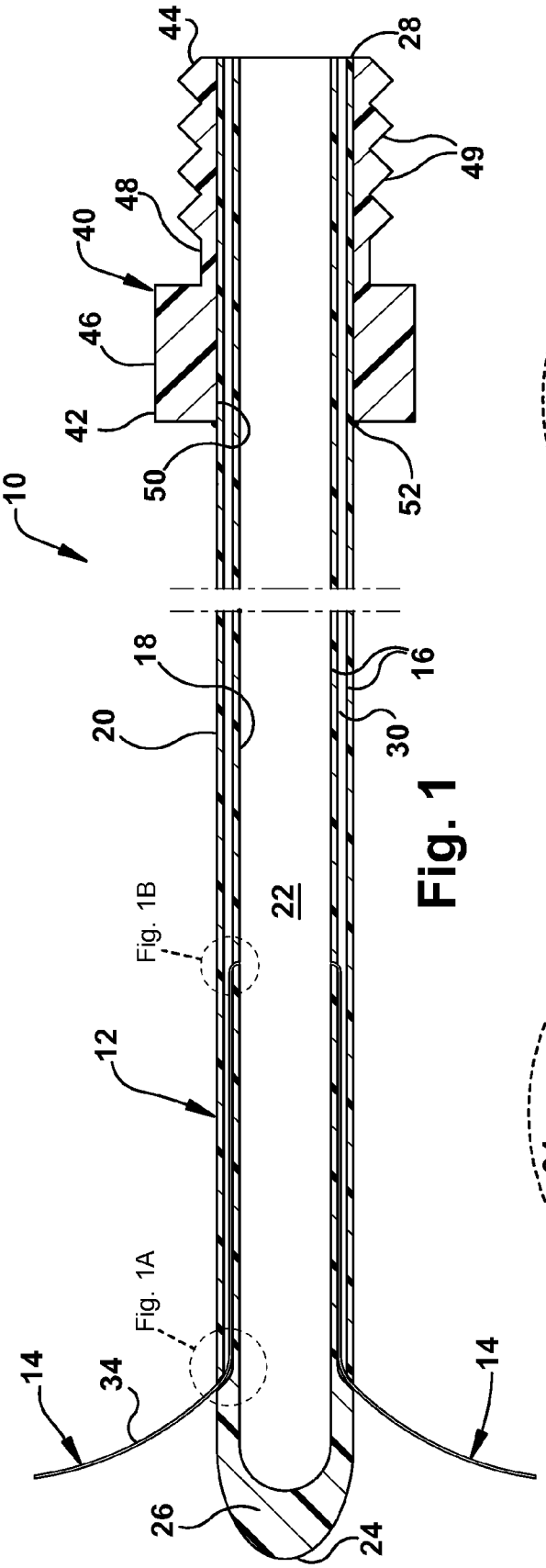

Fig. 1

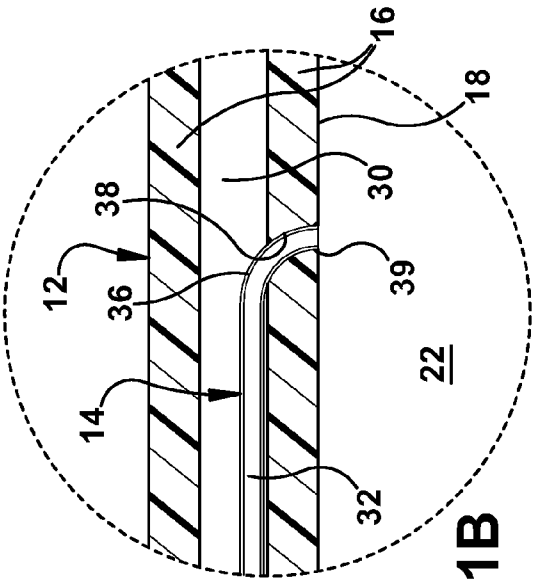

Fig. 1B

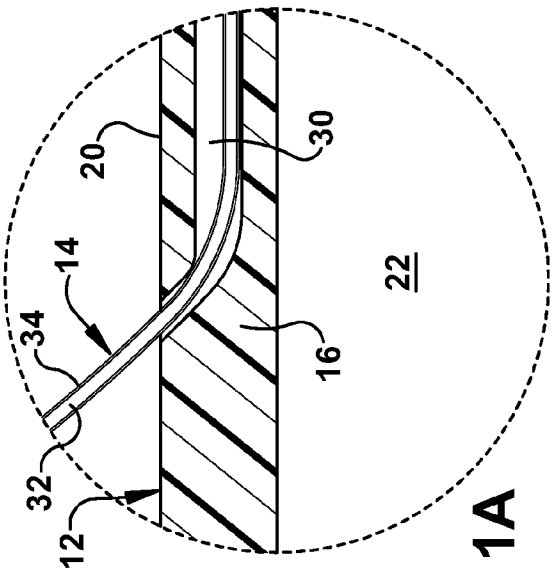

Fig. 1A

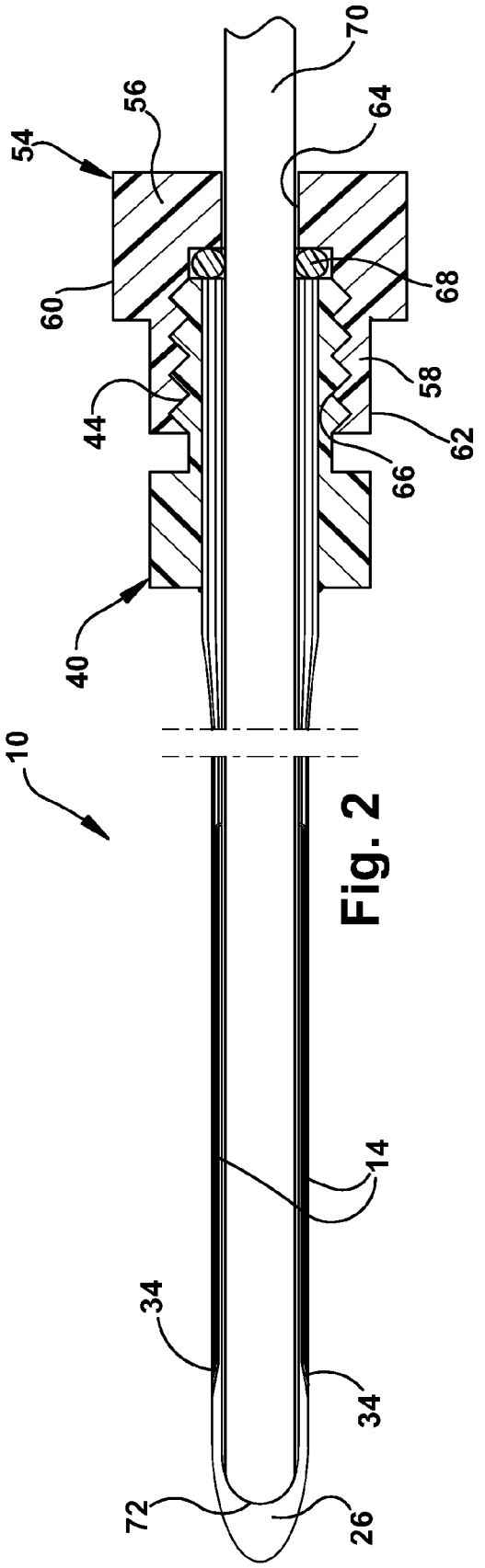
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Fig. 2

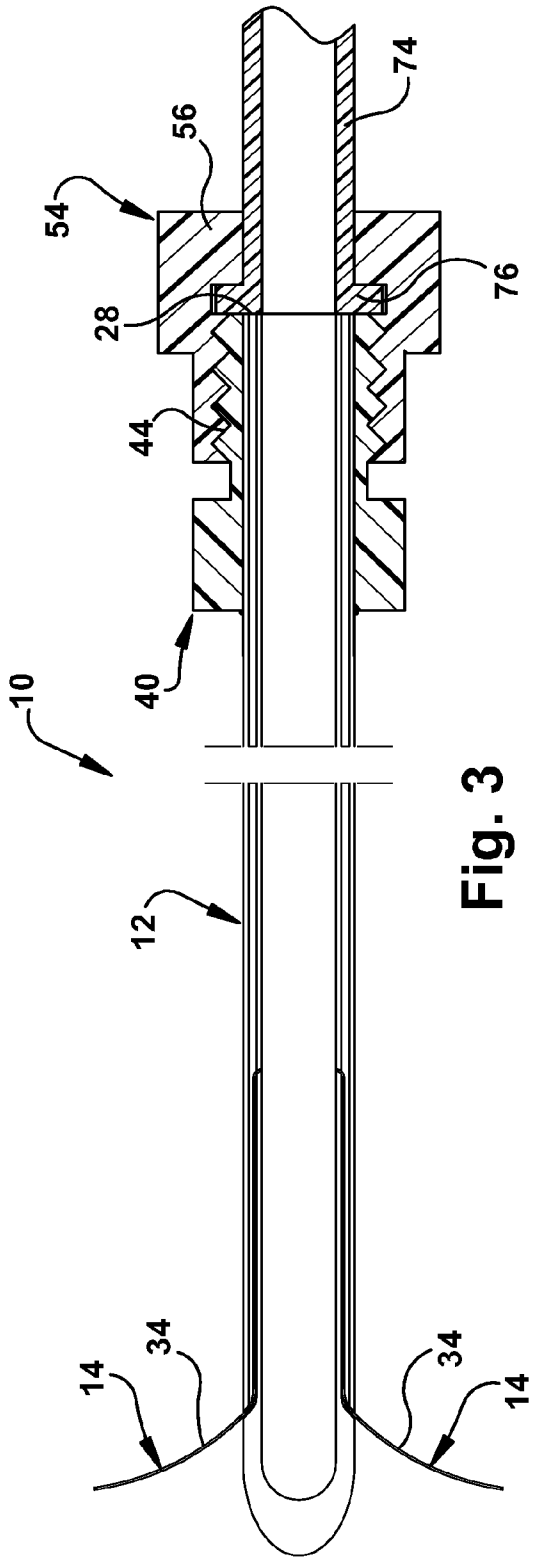
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Fig. 3

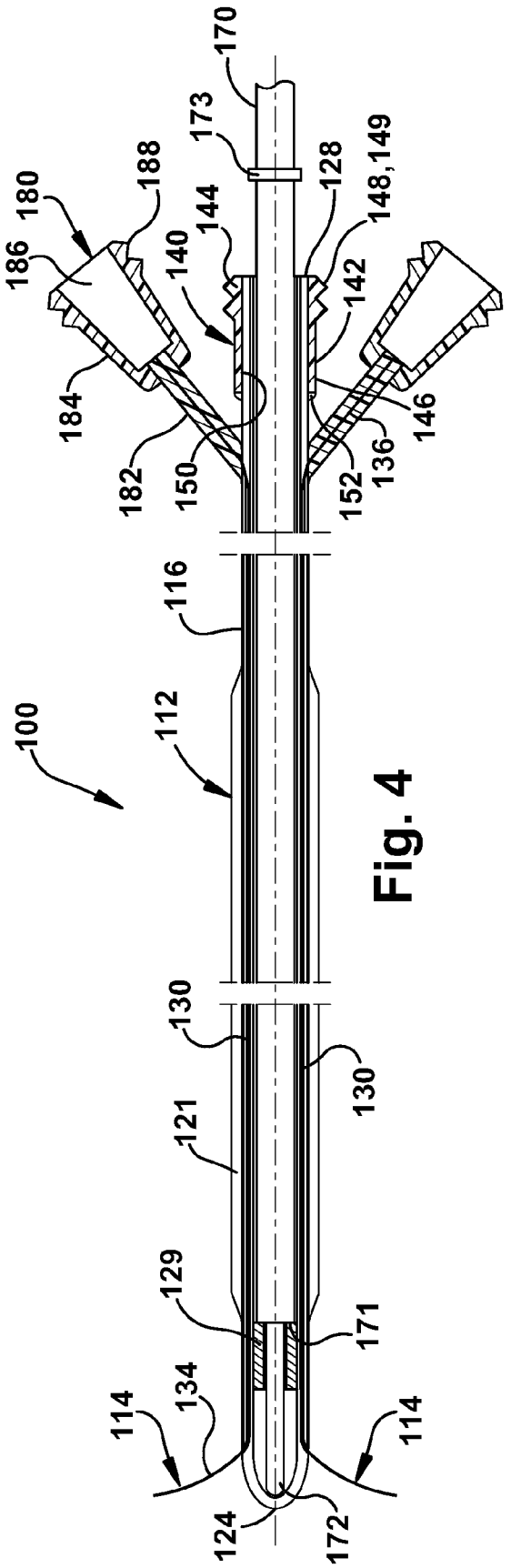
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Fig. 4

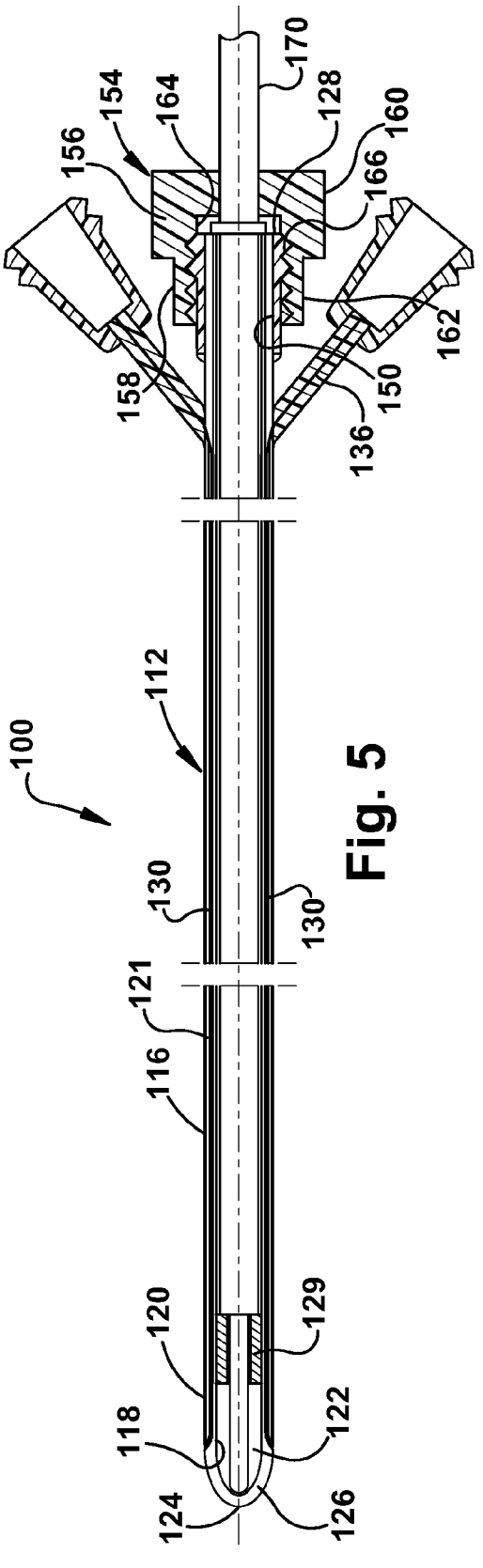
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Fig. 5

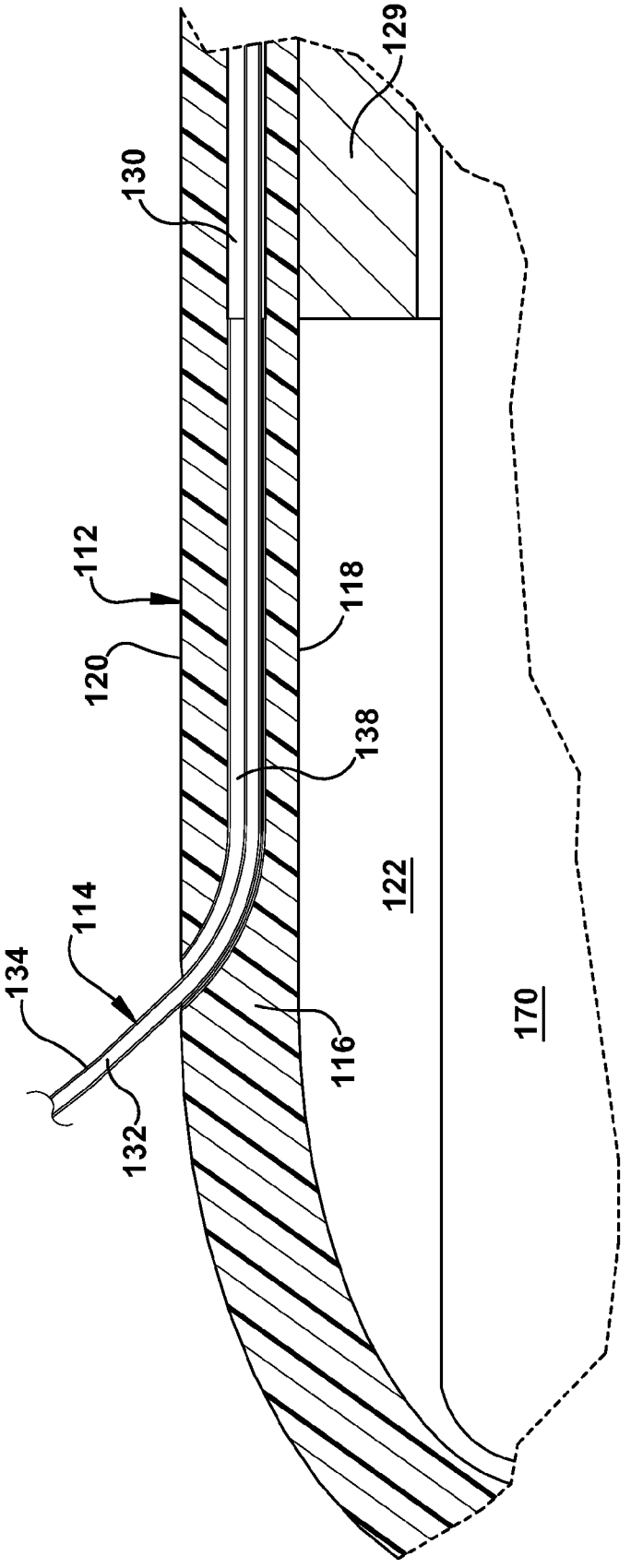

Fig. 4A

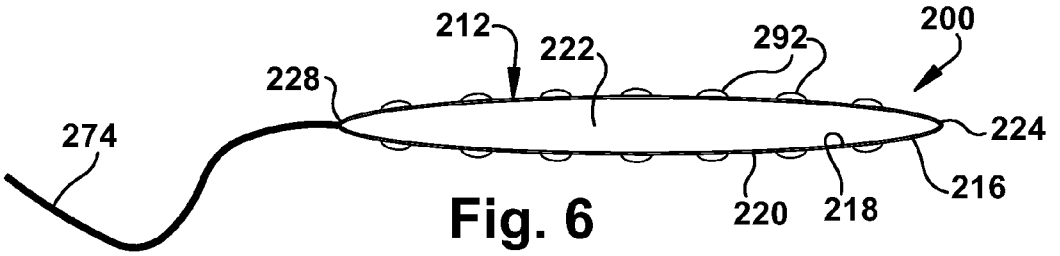

Fig. 6

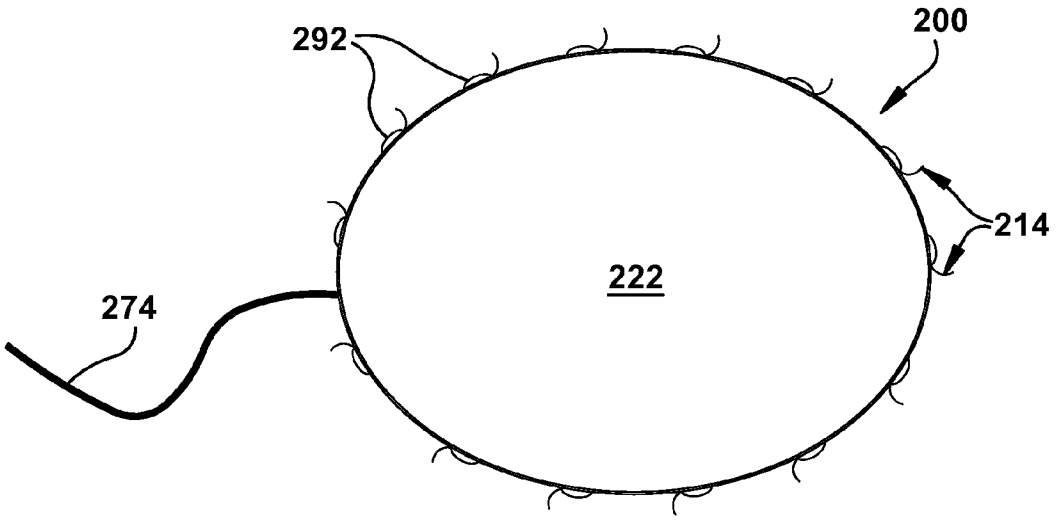

Fig. 7

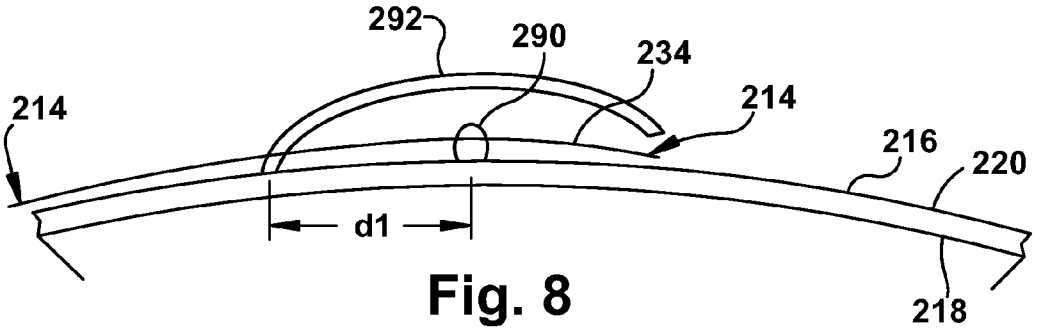

Fig. 8

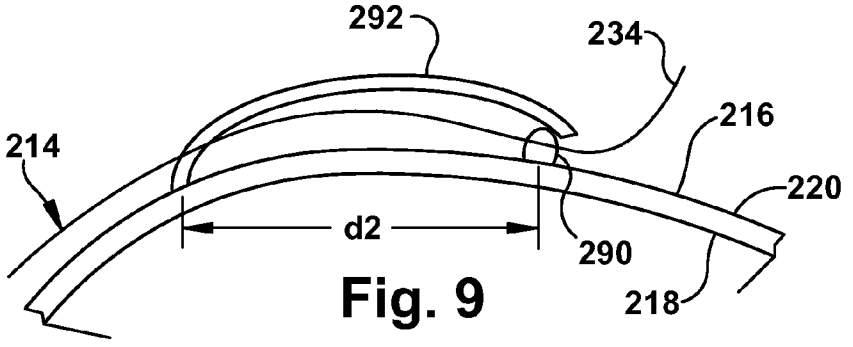

Fig. 9

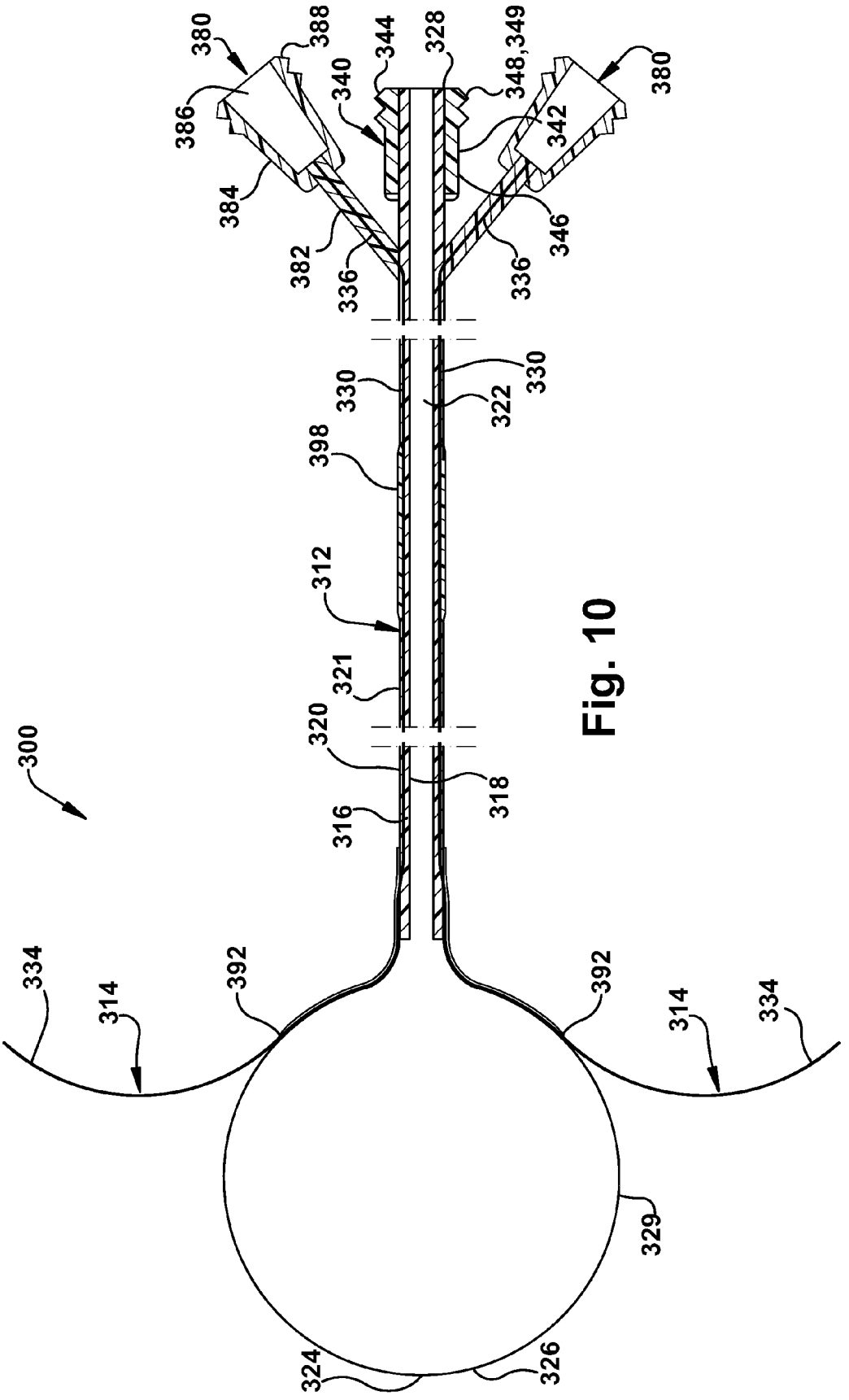
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Fig. 10

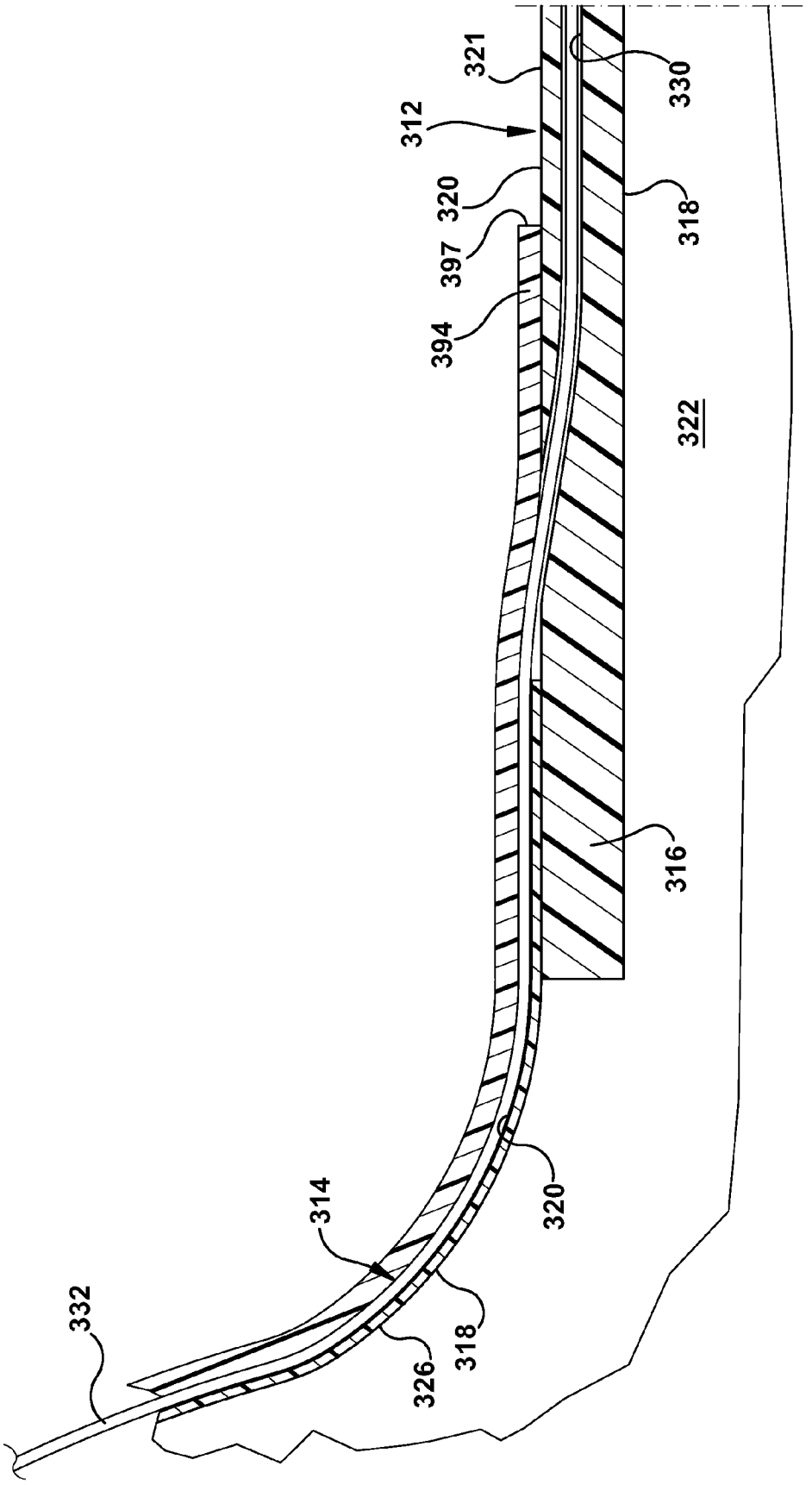

Fig. 10A

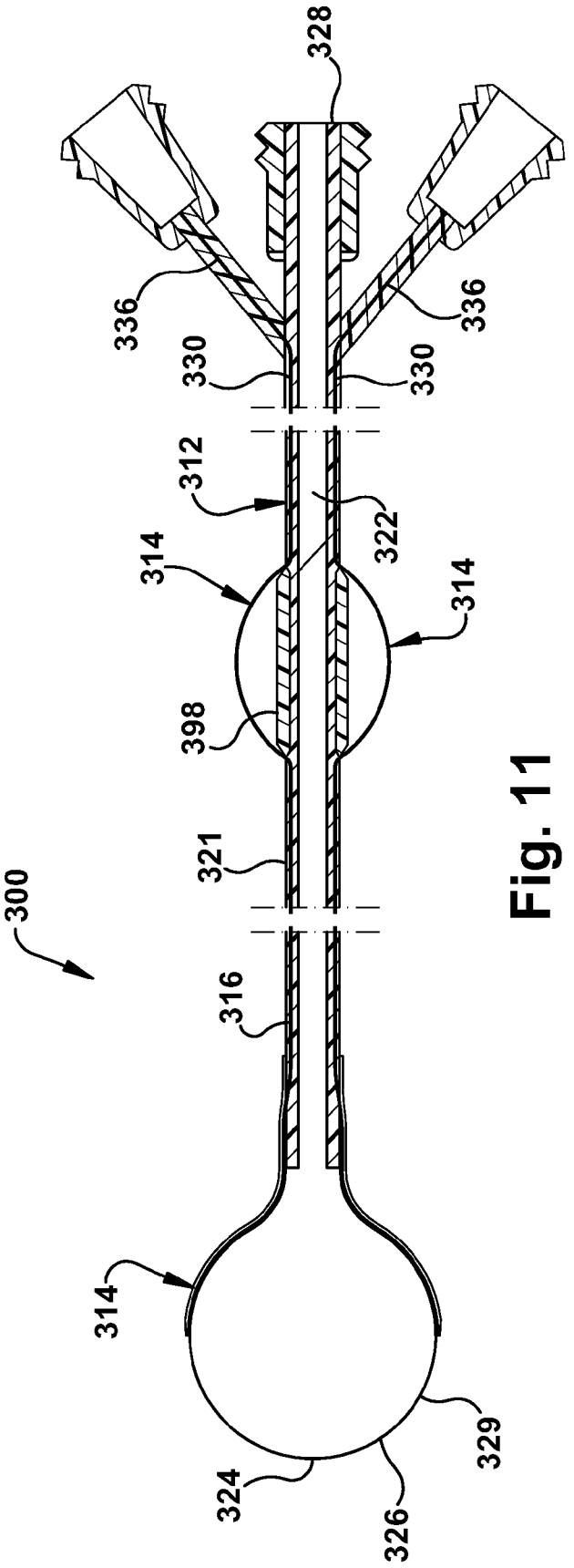
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Fig. 11

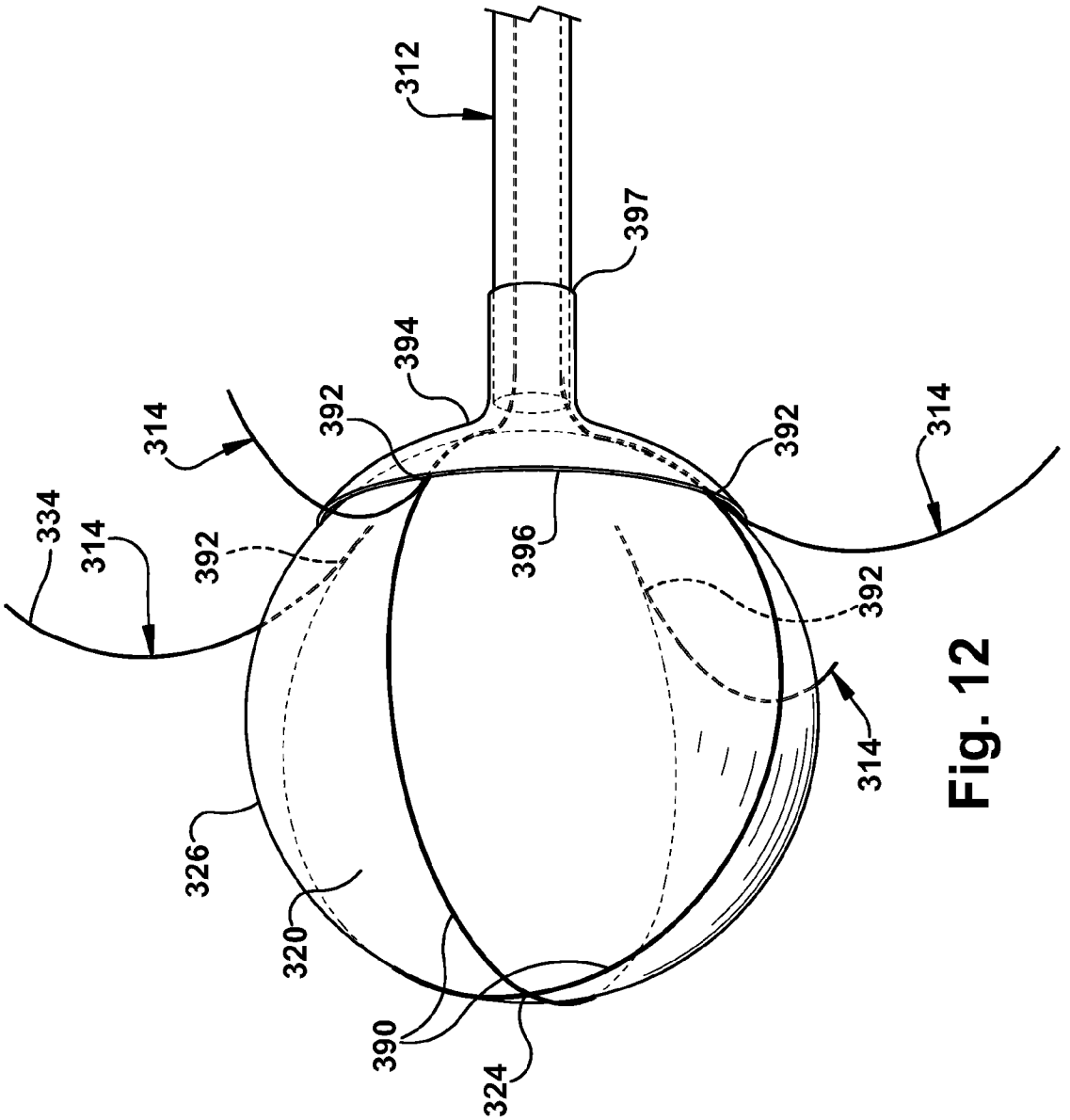

Fig. 12

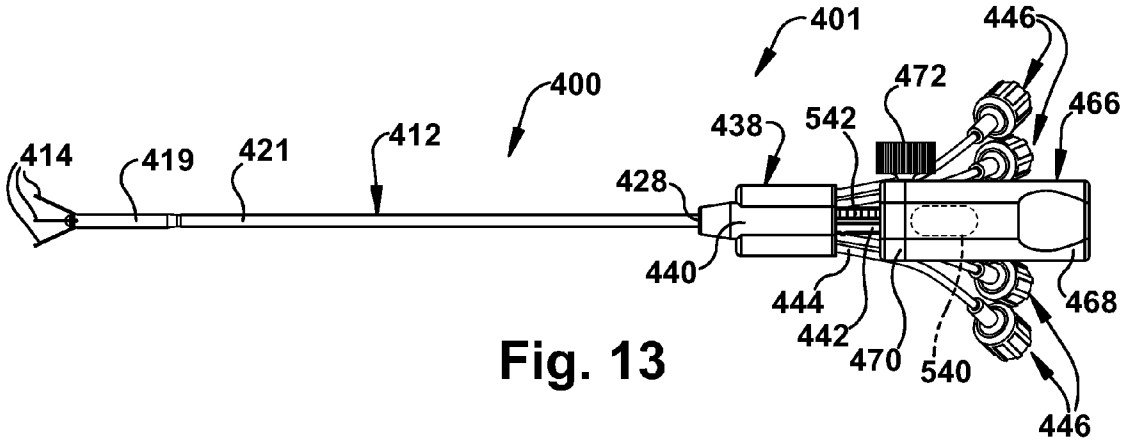

Fig. 13

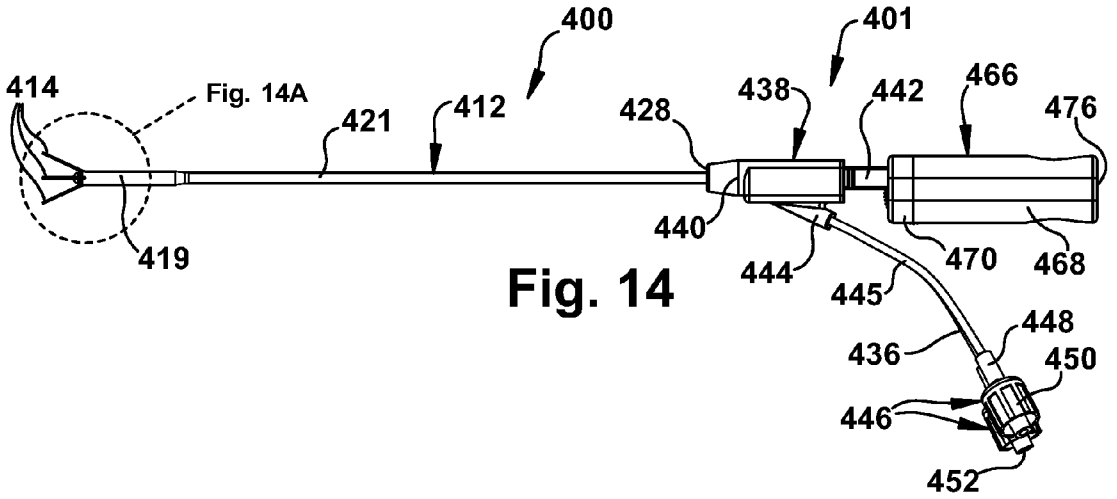

Fig. 14

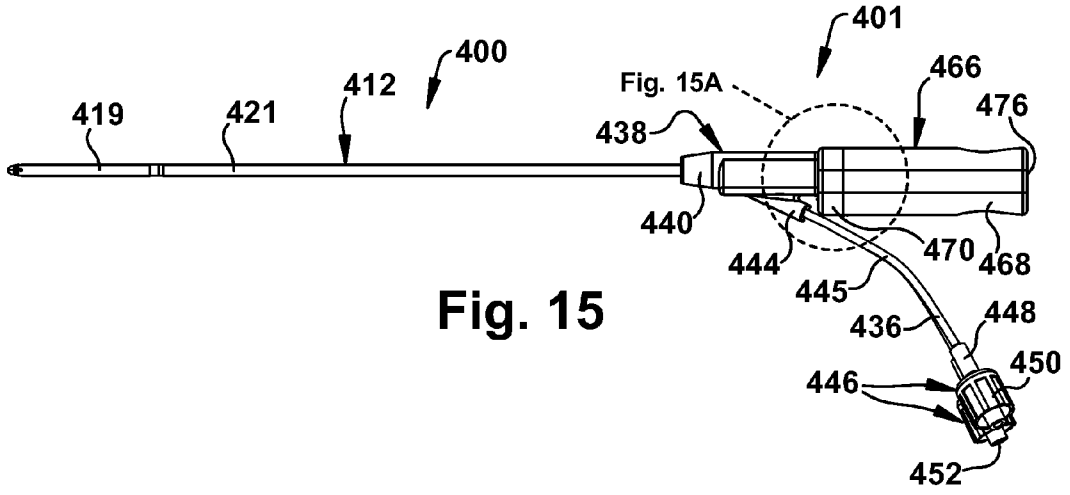

Fig. 15

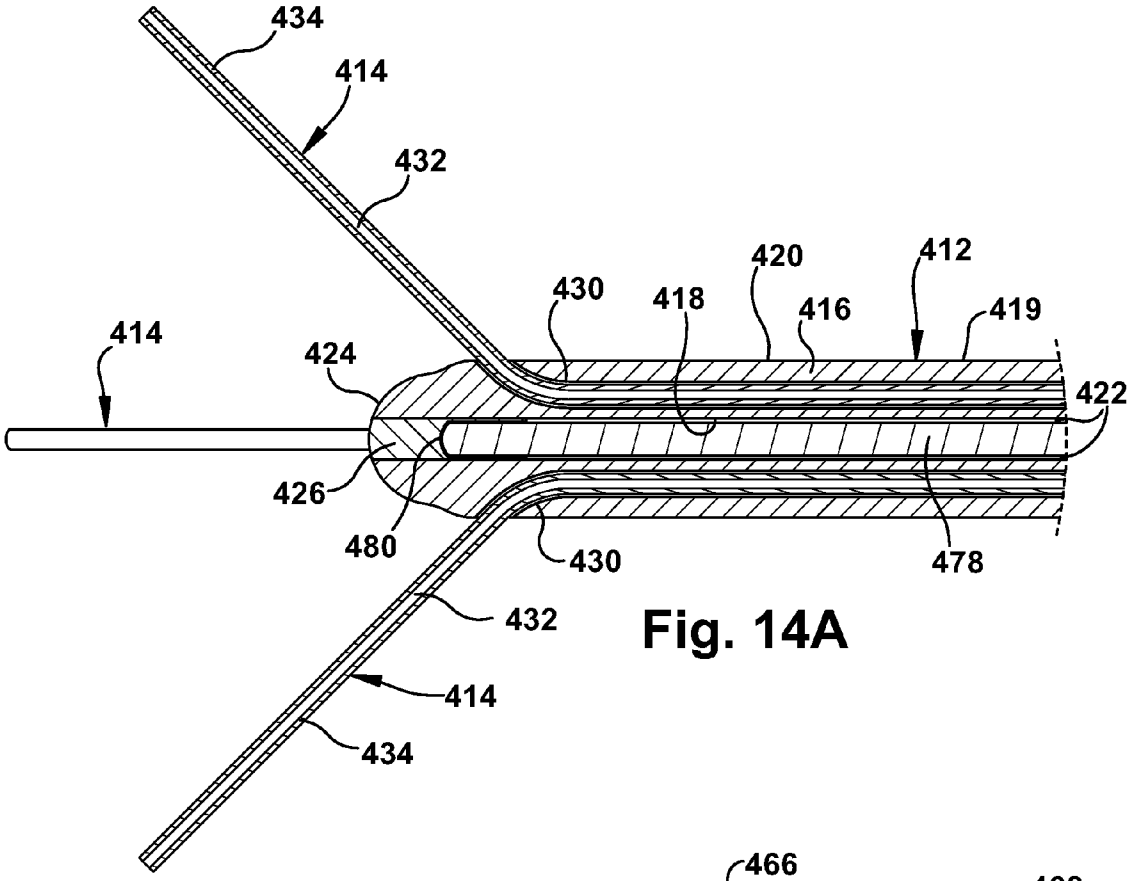

Fig. 14A

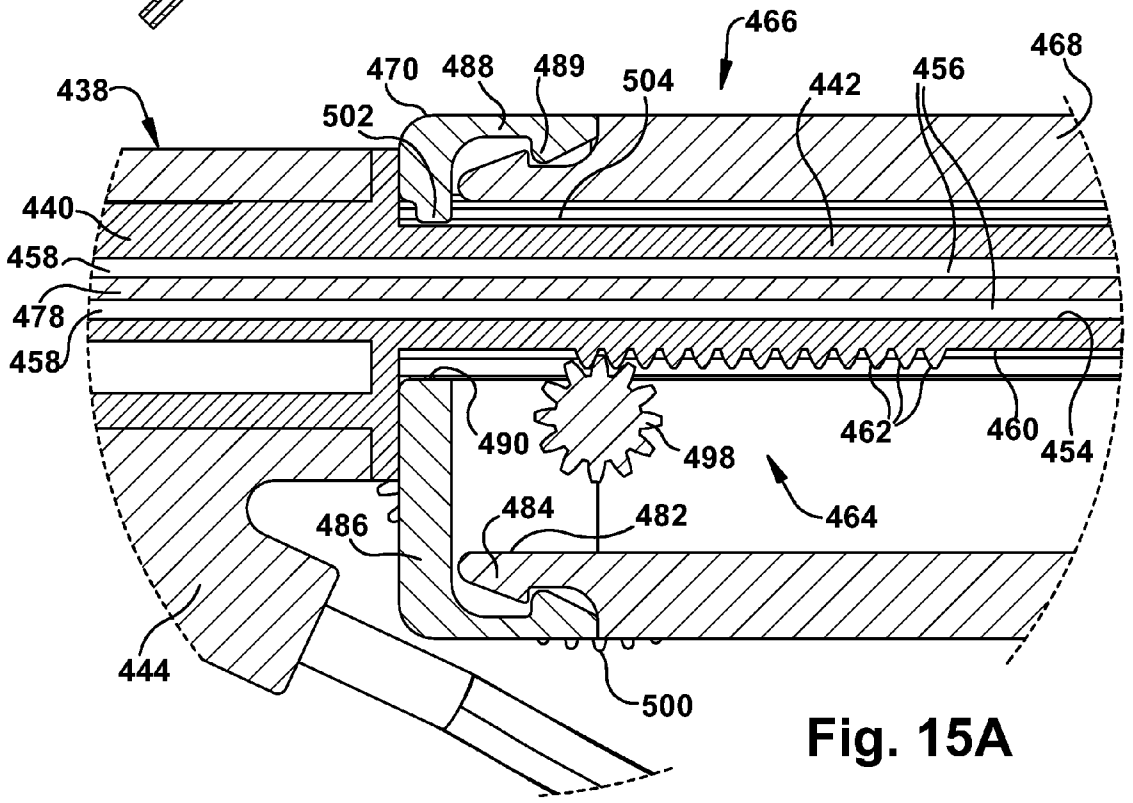

Fig. 15A

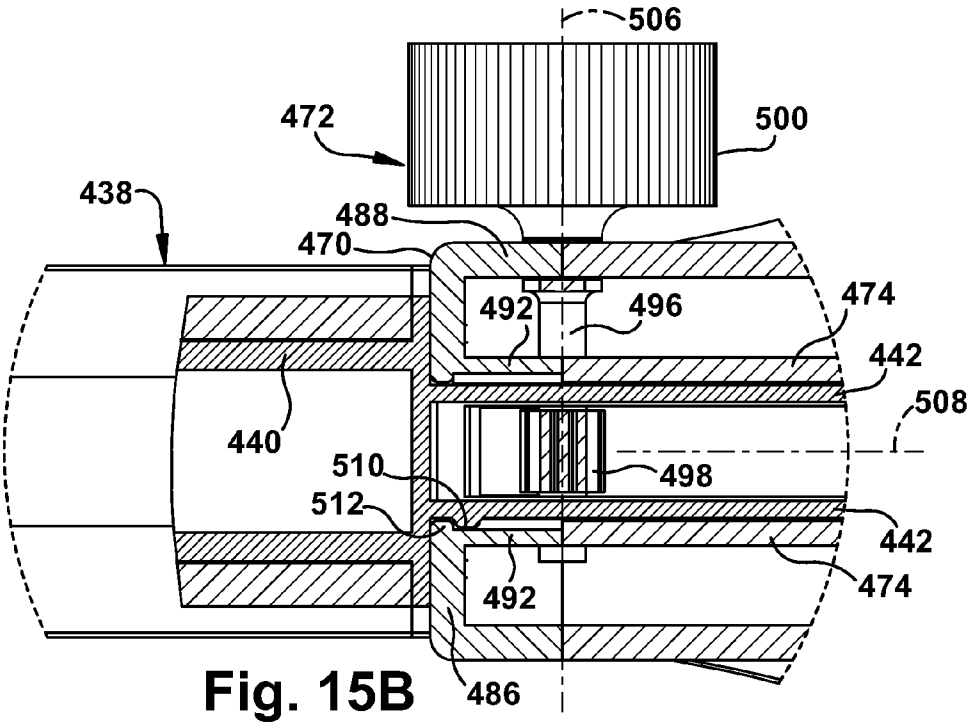

Fig. 15B

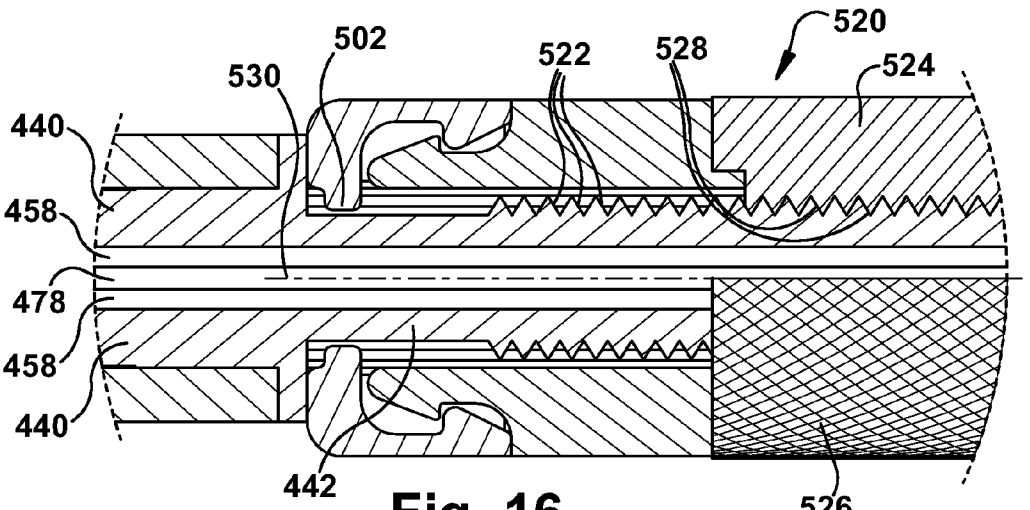

Fig. 16

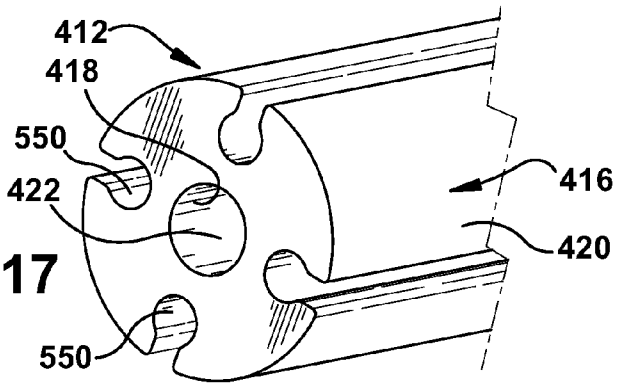

Fig. 17

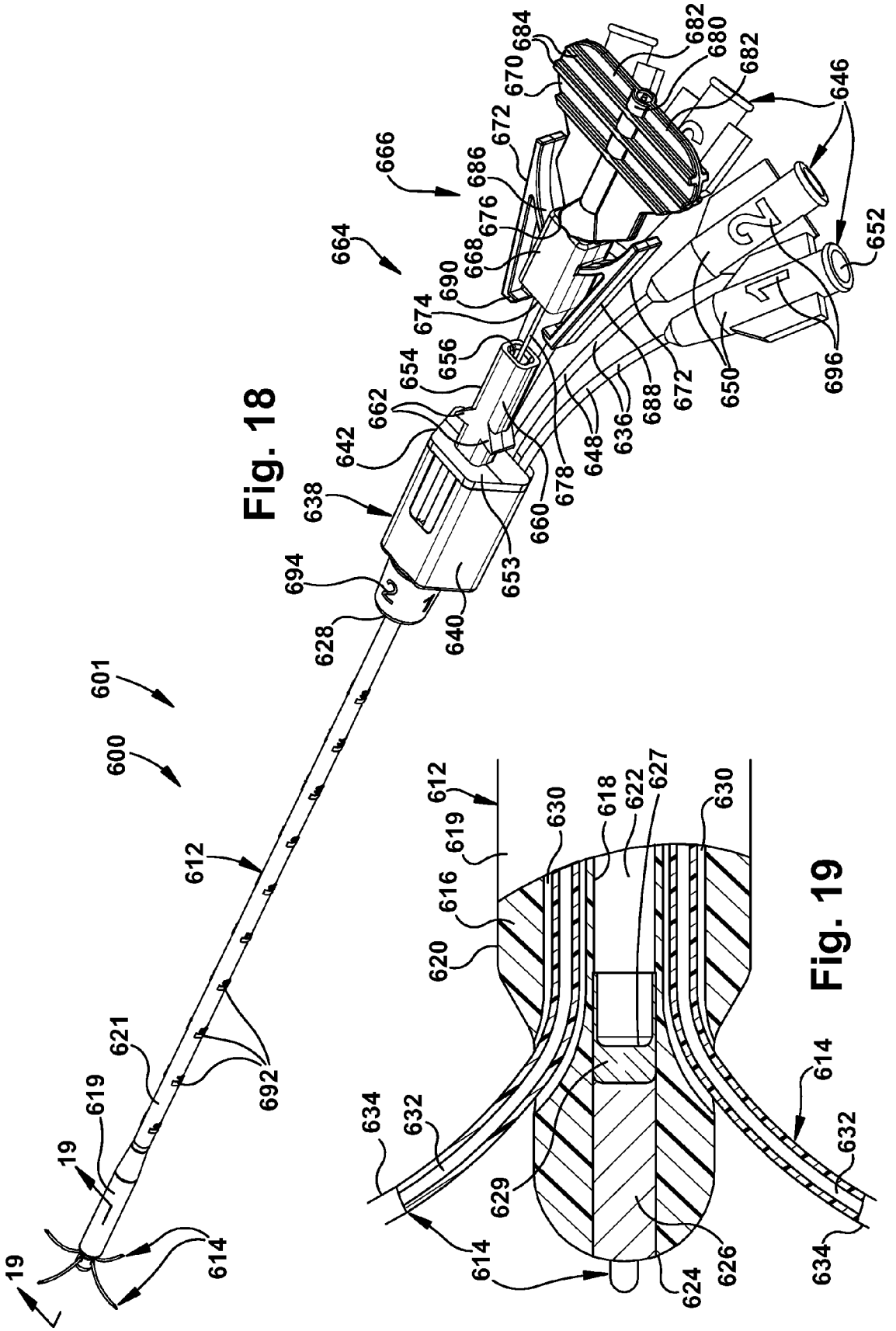
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Fig. 18

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Fig. 19

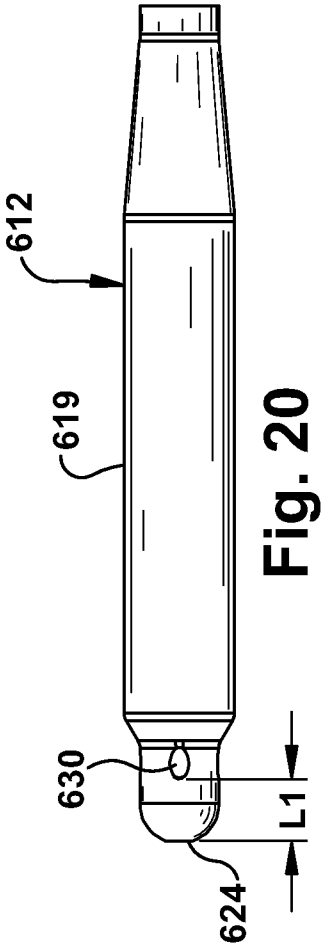

Fig. 20

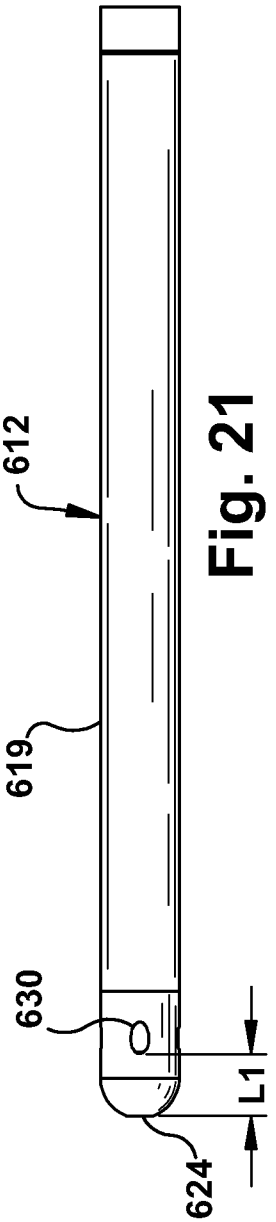

Fig. 21

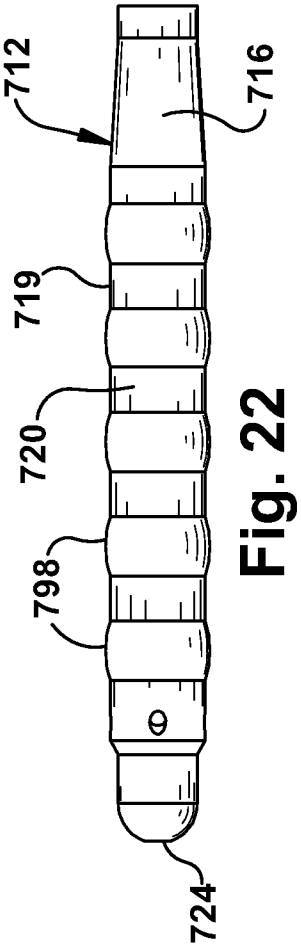

Fig. 22

CATHETER ASSEMBLY

RELATED APPLICATIONS

This application claims priority from U.S. Provisional Patent Application Ser. No. 61/493,777, filed 6 Jun. 2011, U.S. patent application Ser. No. 13/044,963, filed 10 Mar. 2011, and U.S. Provisional Patent Application Ser. No. 61/312,401, filed 10 Mar. 2010. The subject matter of the aforementioned applications is hereby incorporated by reference in their entireties.

JOINT RESEARCH AGREEMENT

The presently claimed invention was made by or on behalf of one or more of the following parties to a joint research agreement: Parker Hannifin Corporation and The Cleveland Clinic Foundation. The joint research agreement was in effect on and before the date the claimed invention was made, and the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement.

FIELD OF THE INVENTION

The present invention relates to a catheter assembly that comprises two connected catheters and, more particularly, to a catheter assembly in which one catheter is at least partially covered by a sheath portion of another catheter.

BACKGROUND OF THE INVENTION

Convection enhanced delivery ("CED") of a bioactive agent involves introducing a fluid containing the bioactive agent into a patient's tissue under pressure so that the fluid moves through the tissue via bulk flow. Implementing CED generally involves inserting multiple catheters into the tissue to be treated, such as cerebral tissue. To reduce the risk of hemorrhage and/or trauma to the tissue, it is desirable for the catheters to be microcatheters with small outside diameters.

SUMMARY OF THE INVENTION

The present invention is directed to a catheter assembly that comprises two connected catheters and, more particularly, to a catheter assembly in which one catheter is at least partially covered by a sheath portion of another catheter.

In accordance with an embodiment of the present invention, a catheter assembly comprises a first catheter including a wall with an inner surface at least partially defining a lumen. A second catheter is connected to the wall of the first catheter and is disposed outward of the inner surface of the wall. The second catheter is at least partially covered by a sheath portion of the first catheter. A first portion of the wall of the first catheter is made of a relatively low durometer elastomeric material and is relatively extensible. A second portion of the wall is formed of a relatively high durometer elastomeric material and is relatively inextensible.

In accordance with another embodiment of the invention, a catheter assembly comprises a first catheter including a wall with an inner surface at least partially defining a lumen extending lengthwise of the first catheter. A second catheter is at least partially disposed in the wall of the first catheter outward of the inner surface of the wall and extending lengthwise of the first catheter. A first portion of the wall of the first catheter is made of a relatively low durometer elastomeric material and is relatively extensible. A second portion of the wall is formed of a relatively high durometer elastomeric material and is relatively inextensible.

In accordance with still another embodiment of the present invention, a catheter assembly comprises a first catheter including a wall with an inner surface at least partially defining a first lumen. A second catheter includes a second lumen. The second lumen is disposed outside of the first lumen, and the first lumen is disposed outside of the second lumen. A first portion of the wall of the first catheter is made of a relatively low durometer elastomeric material and being relatively extensible. A second portion of the wall is formed of a relatively high durometer elastomeric material and is relatively inextensible. The second catheter is connected to the first portion of the wall of the first catheter. Extension of the first portion of the wall causes relative movement between the first portion of the wall and an adjacent, outwardly disposed portion of the second catheter.

In accordance with yet another embodiment of the present invention, a catheter apparatus comprises a first catheter including a wall with an inner surface at least partially defining a lumen. A first portion of the wall of the first catheter is made of a relatively low durometer elastomeric material and is relatively extensible. A second portion of the wall is formed of a relatively high durometer elastomeric material and is relatively inextensible. A second catheter is connected to the wall of the first catheter and is disposed outward of the inner surface of the wall. The second catheter is at least partially covered by a sheath portion of the first catheter. A control mechanism engages a stylet when disposed in the lumen and controls relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall.

In accordance with a further embodiment of the present invention, a catheter apparatus comprises a first catheter including a wall with an inner surface at least partially defining a lumen extending lengthwise of the first catheter. A first portion of the wall of the first catheter is made of a relatively low durometer elastomeric material and is relatively extensible. A second portion of the wall is formed of a relatively high durometer elastomeric material and is relatively inextensible. A second catheter is at least partially disposed in the wall of the first catheter outward of the inner surface of the wall and extending lengthwise of the first catheter. A control mechanism engages a stylet when disposed in the lumen and controls relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall.

In accordance with yet a further embodiment of the present invention, a catheter apparatus comprises a first catheter including a wall with an inner surface at least partially defining a first lumen extending lengthwise of the first catheter. A first portion of the wall of the first catheter is made of a relatively low durometer elastomeric material and is relatively extensible. A second portion of the wall is formed of a relatively high durometer elastomeric material and is relatively inextensible. A second catheter includes a second lumen. The second catheter is disposed outside of the first lumen, and the first lumen is disposed outside of the second lumen. The second catheter is connected to the first portion of the wall of the first catheter. Extension of the first portion of the wall causes relative movement between the first portion of the wall and an adjacent, outwardly disposed portion of the second catheter. A control mechanism engages a stylet when disposed in the first lumen and controls relative movement

between the stylet and the first portion of the wall and consequent extension of the first portion of the wall.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features and advantages of the present invention will become apparent to one skilled in the art upon consideration of the following description of the invention and the accompanying drawings, in which:

FIG. **1** is a sectional view of a first embodiment of a catheter assembly in accordance with the present invention;

FIG. **1**A is an enlarged sectional view of a first portion of the catheter assembly of FIG. **1**;

FIG. **1**B is an enlarged sectional view of a second portion of the catheter assembly of FIG. **1**;

FIG. **2** is a sectional view of the catheter assembly of FIG. **1** in a longitudinally extended condition;

FIG. **3** is a sectional view of the catheter assembly of FIG. **1** in a non-extended condition;

FIG. **4** is a sectional view of a second embodiment of a catheter assembly in accordance with the present invention showing the catheter assembly in a non-extended condition;

FIG. **4**A is an enlarged sectional view of a portion of the catheter assembly of FIG. **4**;

FIG. **5** is a sectional view of the catheter assembly of FIG. **4** in a longitudinally extended condition;

FIG. **6** is a schematic view of a third embodiment of a catheter assembly in accordance with the present invention showing the catheter assembly in a non-extended condition;

FIG. **7** is a schematic view of the catheter assembly of FIG. **6** in an extended condition;

FIG. **8** is an enlarged schematic view of a portion of the catheter assembly of FIG. **6**;

FIG. **9** is an enlarged schematic view of a portion of the catheter assembly of FIG. **7**;

FIG. **10** is a sectional view of a fourth embodiment of a catheter assembly in accordance with the present invention showing the catheter assembly in an extended condition;

FIG. **10**A is an enlarged sectional view of a portion of the catheter assembly of FIG. **10**;

FIG. **11** is a sectional view of the catheter assembly of FIG. **10** in a non-extended condition;

FIG. **12** is a perspective view of a portion of the catheter assembly of FIG. **10**;

FIG. **13** is a top plan view of a fifth embodiment of a catheter assembly in accordance with the present invention showing the catheter assembly in a non-extended condition;

FIG. **14** is a side elevational view of the catheter assembly of FIG. **13**;

FIG. **14**A is an enlarged sectional view of a portion of the catheter assembly of FIG. **14**;

FIG. **15** is a side elevational view of the catheter assembly of FIG. **13** in an extended condition;

FIG. **15**A is an enlarged sectional view of a portion of the catheter assembly of FIG. **15**;

FIG. **15**B is a sectional view, in a plane perpendicular to the plane of FIG. **15**A, of the portion of the catheter assembly of FIG. **15**A;

FIG. **16** is sectional view, similar to FIG. **15**A, of an alternate construction of the portion of the catheter assembly of FIG. **15**;

FIG. **17** is a perspective view of an alternative construction of a portion of the catheter assembly of FIGS. **13** to **15**;

FIG. **18** is a perspective view of a sixth embodiment of a catheter assembly in accordance with the present invention showing the catheter assembly in a non-extended condition;

FIG. **19** is an enlarged sectional view of a portion of the catheter assembly of FIG. **18**;

FIG. **20** is a side view of a larger portion of the catheter assembly of FIG. **18** in a non-extended condition;

FIG. **21** is another side view of the portion of the catheter assembly shown in FIG. **20**, but in an extended condition; and

FIG. **22** is a side view of an alternative construction of the portion of the catheter assembly shown in FIG. **20**.

DETAILED DESCRIPTION

FIGS. **1** through **3** illustrate a catheter assembly **10**, in accordance with an example of the present invention. The catheter assembly **10** includes a first or central catheter **12** and second or peripheral catheters **14**, two of which are shown in FIG. **1**. The central catheter **12** is made of a flexible and resilient biocompatible material, such as a medical grade silicone elastomer, and includes a longitudinally extending, tubular wall **16**. The tubular wall **16** includes a radially inner surface **18** and a radially outer surface **20**. Both the inner surface **18** and the outer surface **20** extend substantially the entire length of the central catheter **12**. The inner surface **18** defines a central lumen **22** that also extends substantially the entire length of the central catheter **12**. The central lumen **22** is closed at a distal end **24** of the central catheter **12** by a thickened end portion **26** of the wall **16**. The central lumen **22** is open at the opposite, proximal end **28** of the central catheter **12**.

Tunnels or passages **30** are formed in the wall **16** of the central catheter **12** and extend generally lengthwise of the central catheter. Two passages **30** are shown in FIG. **1** at diametrically opposite positions about the circumference of the wall **16**. The wall **16** of the central catheter **12** may include more or fewer such passages **30**, as desired. Each of the passages **30** is substantially identical in construction to the other passages **30**. The passages **30** will therefore be described with reference to the passage **30** located uppermost in FIG. **1**, portions of which are shown in enlarged views in FIGS. **1**A and **1**B.

Each passage **30** receives an associated peripheral catheter **14**. The peripheral catheter **14** is thus disposed in the wall **16** of the central catheter **12**, radially outward of the inner surface **18** of the wall **16** and, for a portion of its length, radially inward of the outer surface **20** of the wall **16**. This portion of the length of the peripheral catheter **14** extends lengthwise substantially parallel to the central catheter **12**. As can be seen from FIGS. **1**A and **1**B, the outer diameter of the peripheral catheter **14** is smaller than the thickness of the wall **16** of the central catheter **12** and smaller than the diameter of the associated passage **30**.

Each peripheral catheter **14** has a central lumen **32**, which is disposed outside of the central lumen **22** of the central catheter **12**. Likewise, the central lumen **22** of the central catheter **12** is disposed outside of the central lumens **32** of the peripheral catheters **14**. Each peripheral catheter **14** is formed of a biocompatible material, such as polytetrafluoroethylene ("PTFE"), that has sufficient rigidity to penetrate a patient's tissue and has also has sufficient flexibility and resilience to withstand being deflected and then return to a non-deflected position.

As best seen in FIGS. **1** and **1**A, a distal end portion **34** of the peripheral catheter **14** can project radially outward of the outer surface **20** of the wall **16** of the central catheter **12** near the distal end **24** of the central catheter. To facilitate such radially outward projection of the peripheral catheter **14**, the passage **30** in the wall **16** of the central catheter **12** turns radially outward and opens onto the outer surface **20** of the

wall **16**. The material of which the peripheral catheter **14** is made is also given a predetermined shape in the distal end portion **34** of the peripheral catheter **14** in the form of an outwardly directed curve or hook.

As best seen in FIGS. **1** and **1**B, a proximal end portion **36** of the peripheral catheter **14** communicates with the central lumen **22** of the central catheter **12** at a location spaced from both the distal end **24** and the proximal end **28** of the central catheter. To facilitate such communication between the peripheral catheter **14** and the central catheter **12**, a short connector passage **38** extends radially inward from the passage **30** in the wall **16** and opens onto the inner surface **18** of the wall **16** of the central catheter. The proximal end portion **36** of the peripheral catheter **14** is inserted into the connector passage **38** until an end surface of the peripheral catheter is flush with the inner surface **18** of the wall **16**. A biocompatible adhesive material **39** fixes the proximal end portion **36** of the peripheral catheter **14** to the wall **16** of the central catheter **12**. The central lumen **32** of the peripheral catheter **14** is thus in fluid communication with the central lumen **22** of the central catheter **12**.

As a result of the foregoing construction, fluid may flow along the central lumen **22** of the central catheter **12**, then into the central lumen **32** in the proximal end portion **36** of the peripheral catheter **14**, and further into the distal end portion **34** of the peripheral catheter. The distal end of the peripheral catheter **14** is open so that fluid may flow out of the open distal end of the peripheral catheter.

The portion of the central catheter **12** adjacent its proximal end **28** is received in a tubular male connector **40**, such as a Luer lock connector. The male connector **40** has an enlarged head portion **42** and an opposite threaded portion **44**. The head portion **42** of the male connector **40** has an outer surface **46** formed in a rounded hexagonal shape with raised, longitudinally extending ridges at the corners of the hexagonal shape to facilitate manipulation of the male connector. The threaded portion **44** of the male connector **40** has an outer surface **48** in which a screw thread **49** is formed. An inner surface **50** of the male connector **40** extends through both the head portion **42** and the threaded portion **44** of the male connector and defines a central passage in the male connector. The portion of the central catheter **12** adjacent the proximal end **28** is received in the central passage of the male connector **40** with the threaded portion **44** of the male connector adjacent the open proximal end **28** of the central catheter and with the head portion **42** of the male connector closer to the distal end **24** of the central catheter **12**. A biocompatible adhesive **52** fixes the head portion **42** of the male connector **40** to the outer surface **20** of the wall **16** of the central catheter **12**.

In use, as shown in FIG. **2**, the threaded portion **44** of the male connector **40** is received in a female connector **54**, such as a female Luer lock connector. Like the male connector **40**, the female connector **54** has an enlarged head portion **56** and an opposite threaded portion **58**. The head portion **56** of the female connector **54** has an outer surface **60** formed in a rounded hexagonal shape with raised, longitudinally extending ridges at the corners of the hexagonal shape to facilitate manipulation of the female connector. The threaded portion **58** of the female connector **54** has a cylindrical outer surface **62**. An inner surface **64** of the female connector **54** extends through both the head portion **56** and the threaded portion **58** of the female connector and defines a central passage in the female connector. The inner surface **64** includes a radial step such that the central passage of the female connector **54** has a larger diameter adjacent the threaded portion **58** of the female connector and a smaller diameter adjacent the head portion **56** of the female connector. A screw thread **66** is formed in the inner surface **64** of the female connector **54** adjacent the threaded portion **58** of the female connector.

The threaded portion **44** of the male connector **40** is received in the threaded portion **58** of the female connector **54** with the screw thread **49** in the outer surface **48** of the threaded portion **44** engaging the screw thread **66** formed in the inner surface **64** of the female connector. An O-ring **68** is received against the inner surface **64** of the female connector **54** in the larger diameter portion of the central passage of the female connector between the end of the threaded portion **44** of the male connector **40** and the head portion **56** of the female connector.

When the catheter assembly **10** is to be inserted into tissue, such as cerebral tissue, of a patient, a stylet **70**, which formed of a relatively strong and rigid material, such as stainless steel, is inserted into the catheter assembly. The stylet **70** is inserted into the central passage of the female connector **54**, past the O-ring **68**, and into the central lumen **22** of the central catheter **12** until a rounded distal end **72** of the stylet contacts the thickened end portion **26** of the wall **16** of the central catheter. After the distal end **72** of the stylet **70** contacts the thickened end portion **26**, the stylet continues to be pushed into the central catheter **12** and against the thickened end portion **26** of the wall **16** of the central catheter. The continued pressure of the stylet **70** against the thickened end portion **26** of the wall **16** causes the resilient material of which the wall **16** is made to stretch and thereby causes the wall **16** to extend or distend axially or lengthwise into a longitudinally extended condition.

Longitudinal stretching of the wall **16** causes the outer diameter of the wall to decrease or be reduced, as can be seen in FIG. **2** by comparing the diameter of the middle portion of the wall with the portion adjacent to the male connector **40**. Stretching of the wall **16** of the central catheter **12** also causes the distal end portions **34** of the peripheral catheters **14** to be withdrawn into the passages **30** in the wall **16**, as can be seen in FIG. **2**, because the proximal end portions **36** of the peripheral catheters **14** are fixed to the wall **16**. As they are withdrawn into the passages **30**, the distal end portions **34** of the peripheral catheters **14** are deflected from their outwardly curving, predetermined shape and are constrained in a generally straight configuration by the wall **16** of the central catheter **12**. When the peripheral catheters **14** have been fully withdrawn or retracted into the wall **16** of the central catheter **12**, the outer surface **20** of the wall **16** of the central catheter appears essentially smooth and uninterrupted. The wall **16** of the central catheter **12** thus functions as a sheath portion of the central catheter and covers the distal end portions **34** of the peripheral catheters **14**.

The stylet **70** can then be used to insert the extended central catheter **12** and the peripheral catheters **14** into the tissue of a patient. To facilitate such use of the stylet **70**, the female connector **54** may be screwed further onto the male connector **40** to cause radially inward bulging of the O-ring **68**. Radially inward bulging of the O-ring **68** causes the O-ring to grip the outer surface of the stylet **70** tightly and thus to hold the stylet longitudinally in position in the extended central catheter **12**. Because the outer diameter of the central catheter **12** has been reduced due to the lengthwise extension or distension of the central catheter, the opening that will be formed in the patient's tissue is smaller than it would be otherwise. Because the distal end portions **34** of the peripheral catheters **14** have been withdrawn into the wall **16** of the central catheter **12**, the peripheral catheters do not interfere with the insertion of the central catheter into the patient's tissue. When the distal end **24** of the central catheter **12** is appropriately positioned in a patient's tissue, the stylet **70** is held so as to maintain the distal

end of the central catheter in position. The female connector **54** may then be at least partially unscrewed from the male connector **40** so that the O-ring **68** no longer tightly grips the outer surface of the stylet **70**. With the stylet **70** held in position and the O-ring **68** no longer tightly gripping the stylet, the resilience of the extended central catheter **12** pulls the proximal end **28** of the central catheter along the stylet toward the distal end **24** of the central catheter. The central catheter **12** thus returns resiliently to its initial, non-extended length while the distal end **24** of the central catheter remains in position.

When the central catheter **12** resiliently returns to its initial, non-extended length and the wall **16** of the central catheter resiliently likewise returns from its longitudinally extended condition to its initial, non-extended length, the distal end portions **34** of the peripheral catheters **14** are no longer withdrawn into the wall **16**. The distal end portions **34** of the peripheral catheters **14** instead project from the outer surface **20** of the wall **16** of the central catheter **12** and again assume their outwardly curved, predetermined shape. As the distal end portions **34** of the peripheral catheters **14** assume their outwardly curved, predetermined shape, the peripheral catheters penetrate the patient's tissue and extend into the patient's tissue away from the central catheter **12** in a radial array. In addition, as the wall **16** of the central catheter **12** resiliently returns to its initial length, the outer diameter of the wall increases from its reduced condition back to its original dimension. The increase in the outer diameter of the wall **16** of the central catheter **12** causes the outer surface **20** of the wall **16** to press tightly against adjacent surfaces of the patient's tissue. The resulting close fit between the outer surface **20** of the wall **16** and the adjacent surfaces of the patient's tissue helps to prevent fluid introduced into the tissue by the peripheral catheters **14** from flowing back along the outer surface of the wall toward the proximal end **28** of the central catheter **12**.

With the central and peripheral catheters **12** and **14** of the catheter assembly **10** appropriately positioned in the patient's tissue, therapeutic treatment of the tissue with a bioactive material can begin. To introduce the bioactive material, the stylet **70** is withdrawn entirely from the central lumen **22** of the central catheter and the catheter assembly **10** and from the female connector **54**. The threaded portion **58** of the female connector **54** is then unscrewed from the threaded portion **44** of the male connector **40** and the O-ring **68** is removed. A length of tubing **74** is inserted into the central passage of the female connector **54** until an enlarged distal end **76** of the tubing **74** engages the head portion **56** of the female connector. When the female connector **54** is again screwed onto the male connector **40**, the enlarged distal end **76** of the tubing **74** is trapped in the central passage of the female connector between the threaded portion **44** of the male connector and head portion **56** of the female connector, as shown in FIG. **3**. As the male and female connectors **40** and **54** are screwed together more tightly, the tubing **74** is sealed against the connectors and against the proximal end **28** of the central catheter **12**.

A proximal end (not shown) of the tubing **74** is then attached to a device (not shown), such as a pump, for delivering a fluid, such as a liquid, under pressure to the catheter assembly **10** and thus into a patient's tissue. The fluid contains a bioactive material, such as a pharmaceutical material, and is delivered from the tubing **74** into the central lumen **22** of the central catheter **12**. From the central catheter **12**, the fluid containing the bioactive material is delivered through the inner surface **18** of the wall **16** of the central catheter into the central lumens **32** of the proximal end portions **36** of the peripheral catheters **14**. The fluid flows along the central lumens **32** of the peripheral catheters **14** until it reaches the open ends of the distal end portions **34** of the peripheral catheters and is thereby introduced into the patient's tissue. When the patient's treatment is completed, the catheter assembly **10** may be removed by disconnecting the tubing **74** from the catheter assembly, reintroducing the stylet **70** into the catheter assembly to extend or distend the central catheter **12**, and then withdrawing the catheter assembly and stylet from the patient's tissue.

FIGS. **4** through **5** illustrate a catheter assembly **100** that is constructed in accordance with a second example of the present invention. The catheter assembly **100** includes a first or central catheter **112** and second or peripheral catheters **114**, two of which are shown in FIGS. **4** and **5**. The central catheter **112** is made of a flexible and resilient biocompatible material, such as such as a medical grade silicone elastomer, and includes a longitudinally extending, tubular wall **116**. The tubular wall **116** includes a radially inner surface **118** and a radially outer surface **120**. Both the inner surface **118** and the outer surface **120** extend substantially the entire length of the central catheter **112**. The outer surface **120** is separated from the inner surface **118** by a greater distance in a middle portion of the central catheter **112** than adjacent its distal and proximal ends **124** and **128**, respectively. As a consequence, the wall **116** has a greater thickness in a middle portion **121** of its length than at either end of the wall.

The inner surface **118** of the wall **116** defines a central lumen **122** that extends substantially the entire length of the central catheter **112**. The central lumen **122** is closed at the distal end **124** of the central catheter **112** by a thickened end portion **126** of the wall **116**. The central lumen **122** is open at the opposite, proximal end **128** of the central catheter **112**. A tubular stopper element **129** is disposed in the central lumen **122** of the central catheter **112** adjacent an end of the thickened middle portion **121** of the wall **116** closest to the distal end **124** of the central catheter. The stopper element **129**, which may be formed of medical grade tubing, is secured to the inner surface **118** of the wall **116** by a biocompatible adhesive (not shown).

As best shown in FIG. **4**A, tunnels or passages **130** are formed in the wall **116** of the central catheter **112** and extend generally lengthwise of the central catheter. Two passages **130** are shown in FIGS. **4** and **5** at diametrically opposite positions about the circumference of the wall **116**. The wall **116** of the central catheter **112** may include more or fewer such passages **130**, as desired. Each of the passages **130** is substantially identical in construction to the other passages **130**. Like the passages **30** of the catheter assembly **10** shown in FIGS. **1-3**, each of the passages **130** receives an associated peripheral catheter **114**. The peripheral catheters **114** are thus disposed in the wall **116** of the central catheter **112**, radially outward of the inner surface **118** of the wall **116** and, for a major portion of their lengths, radially inward of the outer surface **120** of the wall **116**. This portion of the lengths of the peripheral catheters **114** extends lengthwise substantially parallel to the central catheter **112**. As can be seen from FIG. **4**A, the outer diameter of each of the peripheral catheters **114** is smaller than the thickness of the wall **116** of the central catheter **112** and smaller than the diameter of the associated passage **130**.

Each peripheral catheter **114** has a central lumen **132**, which is disposed outside of the central lumen **122** of the central catheter **112**. Likewise, the central lumen **122** of the central catheter **112** is disposed outside of the central lumens **132** of the peripheral catheters **114**. Each peripheral catheter **114** is formed of a biocompatible material, such as PTFE, that

has sufficient rigidity to penetrate a patient's tissue and also has sufficient flexibility and resilience to withstand being deflected and then return to a non-deflected position.

As best seen in FIGS. **4** and **4**A, a distal end portion **134** of each peripheral catheter **114** can project radially outward of the outer surface **120** of the wall **116** of the central catheter **112** near the distal end **124** of the central catheter. To facilitate such radially outward projection of the peripheral catheter **114**, the passage **130** in the wall **116** of the central catheter **112** curves radially outward and opens onto the outer surface **120** of the wall **116**. A short length of tubing **138**, such as PTFE tubing, is positioned in the radially curved portion of the passage **130** and is bonded to the wall **116** to act as a bearing surface for sliding movement of the peripheral catheter **114** relative to the wall **116**. The distal end portion **134** of the peripheral catheter **114** is given a predetermined shape in the form of an outwardly directed curve or hook.

Unlike the peripheral catheters **14** of the catheter assembly **10**, the central lumen **132** of the proximal end portion **136** of each peripheral catheter **114** does not communicate with the central lumen **122** of the central catheter **112**. Instead, the proximal end portion **136** of each peripheral catheter **114** projects radially outward of the outer surface **120** of the wall **116** of the central catheter **112** near the proximal end **128** of the central catheter. The proximal end portion **136** of each peripheral catheter **114** is associated with a fluid inlet port or injection port assembly **180**, which receives the proximal end portion of its associated peripheral catheter.

Each injection port assembly **180** includes a sleeve portion **182** and connector portion **184**, such as a Luer lock connector. The sleeve portion **182** and connector portion **184** of each injection port assembly **180** are joined to one another and may be formed in one piece. The sleeve portion **182** of each injection port assembly **180** is elongated and extends between its associated connector portion **184** and an area on the outer surface **120** of the wall **116** of the central catheter **112** from which the proximal end portion **136** of the associated peripheral catheter **114** projects. The sleeve portion **182** surrounds and is bonded to the proximal end portion **136** of the associated peripheral catheter **114** and helps to protect the proximal end portion. The sleeve portion **182** is also adhesively bonded or otherwise secured to the outer surface **120** of the wall **116** of the central catheter **112**, thereby fixing the proximal end portion **136** of the associated peripheral catheter **114** to the wall **116** of the central catheter.

The proximal end portion **136** of each peripheral catheter **114** extends into the connector portion **184** of its associated injection port assembly **180**. The central lumen **132** of the peripheral catheter **114** communicates with a central lumen **186** in the connector portion **184** of the injection port assembly **180**. An outer surface **188** of the connector portion **184** is threaded to facilitate attachment of a second connector (not shown) and tubing (not shown) for delivering a fluid to the connector portion and thus to the peripheral catheter **114**. Such a fluid may flow along the central lumen **132** of the peripheral catheter **114** from its proximal end portion **136** into the distal end portion **134** of the peripheral catheter. The distal end of the peripheral catheter **114** is open so that fluid may flow out of the open distal end of the peripheral catheter.

The portion of the central catheter **112** adjacent the proximal end **128** is received in a tubular male connector **140**, such as a male Luer lock connector. The male connector **140** has a head portion **142** and an opposite threaded portion **144**. The head portion **142** of the male connector **140** has an outer surface **146** formed for manual manipulation to facilitate attachment of another connector, as shown in FIG. **5**. The threaded portion **144** of the male connector **140** has an outer surface **148** in which a screw thread **149** is formed. An inner surface **150** of the male connector **140** extends through both the head portion **142** and the threaded portion **144** of the male connector and defines a central passage in the male connector. The portion of the central catheter **112** adjacent its proximal end **128** is received in the central passage of the male connector **140** with the threaded portion **144** of the male connector adjacent the open proximal end of the central catheter and with the head portion **142** of the male connector closer to the distal end **124** of the central catheter **112**. A biocompatible adhesive **152** fixes the head portion **142** of the male connector **140** to the outer surface **120** of the wall **116** of the central catheter **112**.

When the catheter assembly **100** is ready to be inserted into tissue, such as cerebral tissue, of a patient, a stylet **170** formed of a relatively strong and rigid material, such as stainless steel, is inserted into the catheter assembly. Near its rounded distal end **172**, the stylet **170** has an annular, radially extending surface **171** that provides a step encircling the stylet. Near its proximal end, the stylet **170** is encircled by an annular stroke limiter **173** that is fixed to the stylet. The stylet **170** is inserted into the central passage of the male connector **140** and then into the central lumen **122** of the central catheter **112** until the radially extending surface **171** contacts the stopper element **129** secured to the inner surface **118** of the wall **116** of the central catheter.

After the radially extending surface **171** of the stylet **170** contacts the stopper element **129**, the stylet continues to be pushed into the central catheter **112** and against the stopper element until the stroke limiter **173** contacts the proximal end **128** of the central catheter and the adjacent end of the threaded portion **144** of the male connector **140**. The continued pressure of the stylet **170** against the stopper element **129** causes the resilient material of which the wall **116** is made to stretch and thereby causes the wall **116** to extend or distend axially or lengthwise into a longitudinally extended condition. This stretching of the wall **116** occurs primarily in the thickened middle portion **121** of the wall because the stopper element **129** is bonded to the inner surface **118** of the wall and effectively transfers the force applied by the stylet to the wall **116** adjacent the end of the middle portion closest to the distal end **124** of the central catheter **112**. Adjacent the opposite end of the thickened middle portion **121** of the wall **116**, the peripheral catheters **114** are adhesively bonded to the sleeve portions **182** of the injection port assemblies **180** and are also adhesively bonded to the surface of the wall **116** that defines the passage **130**. These adhesive bonds effectively restrict or prevent stretching of the wall **116** adjacent the proximal end **128** of the central catheter **112**.

Stretching of the wall **116** causes the outer diameter of the wall to decrease or be reduced, as can be seen in FIG. **5** by comparing the diameter of the middle portion **121** of the wall with the portion adjacent the stopper element **129**. Stretching of the wall **116** of the central catheter **112** also causes the distal end portions **134** of the peripheral catheters **114** to be withdrawn into the passages **130** in the wall **116**, as shown in FIG. **5**, because the proximal end portions **136** of the peripheral catheters are fixed to the injection port assemblies **180** and to the surfaces of the wall **116** that define the passages. As they are withdrawn into the passages **130**, the distal end portions **134** of the peripheral catheters **114** are deflected from their outwardly curving, predetermined shape and are constrained in a generally straight configuration by the wall **116** of the central catheter **112**. When the peripheral catheters **114** have been fully withdrawn or retracted into the wall **116** of the central catheter **112**, the outer surface **120** of the wall **116** of the central catheter appears essentially smooth and

uninterrupted. The wall **116** of the central catheter **112** thus functions as a sheath portion of the central catheter and covers the distal end portions **134** of the peripheral catheters **114**.

When the stylet **170** reaches the end of its stroke, as determined by contact between the stroke limiter **173** and the proximal end **128** of the central catheter and the adjacent end of the threaded portion **144** of the male connector **140**, the stylet may be secured in place to facilitate coordinated manipulation of the stylet and the catheter assembly **100**. As best seen in FIG. **5**, the threaded portion **144** of the male connector **140** may be received in a female connector **154**. The female connector **154** has an enlarged head portion **156** and an opposite threaded portion **158**. The head portion **156** of the female connector **154** has an outer surface **160** formed in a rounded hexagonal shape with raised, longitudinally extending ridges at the corners of the hexagonal shape to facilitate manipulation of the female connector. The threaded portion **158** of the female connector **54** has a cylindrical outer surface **162**. An inner surface **164** of the female connector **154** extends through both the head portion **156** and the threaded portion **158** of the female connector and defines a central passage in the female connector. The inner surface **164** includes a radial step such that the central passage of the female connector **154** has a larger diameter adjacent the threaded portion **158** of the female connector and a smaller diameter adjacent the head portion **156** of the female connector. A screw thread **166** is formed in the inner surface **164** of the female connector **154** adjacent the threaded portion **158** of the female connector.

The threaded portion **144** of the male connector **140** is received in the threaded portion **158** of the female connector **154** with the screw thread **149** in the outer surface **148** of the threaded portion **144** engaging the screw thread **166** formed in the inner surface **164** of the female connector. An annular washer (not shown), which may be formed of PTFE, for example, may be received against the inner surface **164** of the female connector **154** in the larger diameter portion of the central passage of the female connector between the end of the threaded portion **144** of the male connector **140** and the head portion **156** of the female connector.

When the female connector **154** is screwed onto the male connector **140**, the stroke limiter **173** of the stylet **170** is trapped between the threaded portion **144** of the male connector and head portion **156** of the female connector. The stylet **170** and the catheter assembly **100** then tend to move more consistently as a single unit and can be manipulated more easily and accurately. In particular, the stylet **170** can then be used to insert the extended central catheter **112** and the peripheral catheters **114** into the tissue of a patient. Because the outer diameter of the central catheter **112** has been reduced due to the lengthwise extension or distension of the central catheter, the opening formed in the patient's tissue is smaller than it would be otherwise. Because the distal end portions **134** of the peripheral catheters **114** have been withdrawn into the wall **116** of the central catheter, the peripheral catheters do not interfere with the insertion of the central catheter into the patient's tissue. When the distal end **124** of the central catheter **112** is appropriately positioned in a patient's tissue, the stylet **170** is held so as to maintain the distal end of the central catheter in position. The female connector **154** may then be unscrewed from the male connector **140** so that the stroke limiter **173** of the stylet **170** is no longer trapped between the threaded portion **144** of the male connector and head portion **156** of the female connector. With the stylet **70** held in position and the stroke limiter **173** no longer trapped between the male and female connectors **140** and **154**, respectively, the resilience of the extended central catheter **112** pulls the proximal end **128** of the central catheter along the stylet toward the distal end **124** of the central catheter. The central catheter **112** thus returns resiliently to its initial, non-extended length while the distal end **124** of the central catheter remains in position.

When the central catheter **112** resiliently returns to its initial, non-extended length and the wall **116** of the central catheter likewise resiliently returns from its longitudinally extended condition to its initial, non-extended length, the distal end portions **134** of the peripheral catheters **114** are no longer withdrawn into the wall **116**. The distal end portions **134** of the peripheral catheters **114** instead project from the outer surface **120** of the wall **116** of the central catheter and assume their outwardly curved, predetermined shape. As the distal end portions **134** of the peripheral catheters **114** assume their outwardly curved, predetermined shape, the peripheral catheters **114** penetrate the patient's tissue and extend into the patient's tissue away from the central catheter **112** in a radial array. In addition, as the wall **116** of the central catheter **112** resiliently returns to its initial length, the outer diameter of the wall, particularly the middle portion **121**, increases from its reduced condition back to its original dimension. The increase in the outer diameter of the wall **116** of the central catheter **112** causes the outer surface **120** of the wall **116** to press tightly against adjacent surfaces of the patient's tissue. The resulting close fit between the outer surface **120** of the wall **116** and the adjacent surfaces of the patient's tissue helps to prevent fluid introduced into the tissue by the peripheral catheters **114** from flowing back along the outer surface of the wall toward the proximal end **128** of the central catheter **112**.

With the central and peripheral catheters **112** and **114** of the catheter assembly **100** appropriately positioned in the patient's tissue, therapeutic treatment of the tissue with a bioactive material can begin. To introduce the bioactive material, the stylet **170** is withdrawn entirely from the central lumen **122** of the central catheter **112** and the catheter assembly **100** and from the male connector **140**. The threaded outer surface **188** of the connector portion **184** of each injection port assembly **180** is connected with a connector (not shown) and the distal end of a length of tubing (not shown). A proximal end (not shown) of the tubing is attached to a device (not shown), such as a pump, for delivering a fluid, such as a liquid. The fluid contains a bioactive material, such as a pharmaceutical material, and is delivered from the tubing into the central lumen **186** of the connector portion **184** of the injection port assembly **180** and then into the central lumen **132** of the associated peripheral catheter **114**. The fluid flows along the central lumen **132** of the peripheral catheter **114** until it reaches the open end of the distal end portion **134** of the peripheral catheter and is thereby introduced into the patient's tissue. When the patient's treatment is completed, the catheter assembly **100** may be removed by reintroducing the stylet **170** into the catheter assembly to extend or distend the central catheter **112** and then withdrawing the catheter assembly from the patient's tissue.

In one particular embodiment of a catheter in accordance with FIGS. **4** through **5**, the central catheter **112** is formed of a medical grade silicone rubber, which is available as product number MED 4901 from Nusil Silicone Technology of Carpinteria, Calif., U.S.A. The nominal outside diameter of the central catheter **112** is between about 2.0 mm and about 2.5 mm. The peripheral catheters **114** are formed of PTFE medical grade tubing with a nominal inside diameter of about 0.203 mm (0.008 inches), a wall thickness of about 0.076 mm (0.003 inches), and a nominal outside diameter of about 0.356 mm (0.014 inches). The distal end portions **134** of the peripheral catheters **114** project outwardly from the outer surface

120 of the wall 116 of the central catheter 112 a distance from about 10 mm to about 20 mm. In areas where the peripheral catheters 114 are to be bonded to the central catheter 112 or another element of the catheter assembly 100, the outer surfaces of the peripheral catheters are etched to enhance bonding and a silicone adhesive, such as product number 1137 from Nusil Silicone Technology of Carpinteria, Calif., U.S.A., is used. The numerical values set forth above and other numerical values set forth in the present application are given by way of example only and other values may be used with satisfactory results.

FIGS. 6 through 9 illustrate a catheter assembly 200 that is constructed in accordance with a third example of the present invention. The catheter assembly 200 includes a first or central catheter 212 and second or peripheral catheters 214, which are shown schematically in FIGS. 7-9. The central catheter 212 is made of a flexible and resilient biocompatible material, such as a medical grade silicone elastomer, and includes a wall 216. The wall 216 includes a radially inner surface 218 and a radially outer surface 220. Both the inner surface 218 and the outer surface 220 extend substantially throughout the central catheter 212. The inner surface 218 defines a central lumen 222 that also extends substantially throughout the central catheter 212.

The central lumen 222 is closed at a distal end 224 of the central catheter 212 by a portion of the wall 216. The central lumen 222 is open at the opposite, proximal end 228 of the central catheter 212. The open proximal end 228 of the central lumen 222 is connected to and communicates with a length of tubing 274. The tubing 274 delivers a fluid to the central lumen 222 for inflating or distending the central catheter 212. When inflated or distended, as shown in FIG. 7, the central catheter 212 resembles a balloon and can occupy a space or volume that has a relatively large radial dimension. The central catheter 212 is thus suitable for use in a tissue cavity, such as a resection cavity from which a tumor has been surgically removed.

Unlike the embodiments of FIGS. 1-3 and FIGS. 4-5, tunnels or passages need not be formed in the wall 216 of the central catheter 212 to receive the peripheral catheters 214. Instead, the peripheral catheters 214 may be positioned against the outer surface 220 of the wall 216 of the central catheter 212, as shown in FIGS. 8 and 9. Each peripheral catheter 214 is thus disposed radially outward of the inner surface 118 of the wall 116 and radially outward of the outer surface 220 of the wall 216. Each peripheral catheter also extends lengthwise in the same general direction as the central catheter 212. As indicated in FIGS. 8 and 9, the outer diameter of each peripheral catheter 214 is smaller than the thickness of the wall 216 of the central catheter 212. Each peripheral catheter 214 has a central lumen (not shown), which is disposed outside of the central lumen 222 of the central catheter 212. Likewise, the central lumen 222 of the central catheter 112 is disposed outside of the central lumens (not shown) of the peripheral catheters 214. Each peripheral catheter 214 is formed of a biocompatible material, such as PTFE, that has sufficient rigidity to penetrate a patient's tissue and also has sufficient flexibility and resilience to withstand being deflected and then return to a non-deflected position.

As best seen in FIG. 9, a distal end portion 234 of each peripheral catheter 214 can project radially outward of the outer surface 220 of the wall 216 of the central catheter 212. To facilitate such radially outward projection of the peripheral catheter 214, the distal end portion 234 of the peripheral catheter is given a predetermined shape in the form of an outwardly directed curve or hook. The distal end portion 234 of each peripheral catheter 214 is also fixed or immovably attached to a point on the outer surface 220 of the wall 216 of the central catheter 212 by an associated attachment 290, such as a small mass of silicone elastomer bonded to the outer surface. Each peripheral catheter 214 has its own, individual attachment point and associated attachment 290.

To constrain the distal end portion 234 of each peripheral catheter 214 and maintain the distal end portion against the wall 216 of the central catheter, the distal end portion is covered by an associated sheath 292. Each sheath 292 is fixed or immovably attached at one end to the outer surface 220 of the wall 216 of the central catheter 212 at a point or along a line adjacent to but spaced apart from the attachment 290 for an associated peripheral catheter 214. The length of each sheath 292 is sufficient that the sheath covers the entire length of the distal end portion 234 of an associated peripheral catheter 214. Each sheath 292 is attached at one or more points or on a line along its length to the outer surface 220 of the wall 216 of the central catheter 212 using a releasable adhesive or other detachable attachment mechanism (not shown) to help maintain the distal end portion 234 of the associated peripheral catheter 214 against the wall 216 of the central catheter.

The peripheral catheters 214 do not communicate with the central lumen 222 of the central catheter 212. Instead, the proximal end portion (not shown) of each peripheral catheter 214 is connected to a device (not shown), such as pump, for delivering a fluid, such as a liquid, under pressure to the catheter assembly 200 and thus into a patient's tissue. The fluid contains a bioactive material, such as a pharmaceutical material, and is delivered to the each of the peripheral catheters 214. Such a fluid may flow along the central lumen (not shown) of the peripheral catheter 214 from adjacent its proximal end portion (not shown) into the distal end portion 234 of the peripheral catheter. The distal end of the peripheral catheter 214 is open so that fluid may flow out of the open distal end of the peripheral catheter.

In use, the central catheter 212 is introduced into a cavity, such as a resection cavity, in the tissue of a patient. The central catheter 212 is introduced into the tissue cavity in an uninflated or partially inflated or distended condition, as shown in FIG. 6. In this condition, the distal end portions 234 of the peripheral catheters 214 lie against the outer surface 220 of the wall 216 of the central catheter 212 and are covered by their associated sheaths 292, as shown in FIG. 8. When the central catheter 212 is appropriately positioned, fluid is introduced into the central lumen 222 of the central catheter to inflate the central catheter. As the central catheter 212 inflates, the wall 216 of the central catheter resiliently stretches or distends. As the wall 216 of the central catheter 212 resiliently distends or extends, the central catheter fills the cavity in the tissue of the patient and the distal end portions 234 of the peripheral catheters 214 are moved closer to the tissue surrounding and defining the cavity in the tissue.

In addition, as the wall 216 of the central catheter 212 resiliently extends or distends and the central catheter inflates, the distance between the fixed attachment point of each sheath 292 and the attachment 290 for the distal end portion 234 of its associated peripheral catheter 214 increases from a first distance (designated "d1" in FIG. 8) to a second, greater distance (designated "d2" in FIG. 9). The movement of the fixed attachment point of each sheath 292 relative to other points on the outer surface 220 of the wall 216 of the central catheter 212 causes the releasable adhesive or other detachable attachment mechanism (not shown) along the length of the sheath to release or detach from the outer surface 220 of the wall 216. The sheath 292 is thereby allowed to

move from a position covering and constraining the distal end portion **234** of its associated peripheral catheter **214**. The sheath **292** may be viewed as effectively withdrawn from a position covering and constraining the distal end portion **234** of its associated peripheral catheter **214**. Alternatively, the distal end portion **234** of the associated peripheral catheter **214** may be viewed as effectively pulled by its associated attachment **290** away from the sheath **292**. Regardless of the point of view, the distal end portions **234** of the peripheral catheters **214** are left free to project away from the outer surface **220** of the wall **216** of the central catheter **212** and assume their outwardly curved, predetermined shape. As the distal end portions **234** of the peripheral catheters **214** assume their outwardly curved, predetermined shape, the peripheral catheters **214** penetrate the patient's tissue and extend into the patient's tissue away from the central catheter **212** in a radial array.

With the central and peripheral catheters **212** and **214** of the catheter assembly **200** appropriately positioned in the patient's tissue, therapeutic treatment of the tissue with a bioactive material can begin. To introduce the bioactive material, the pump or other device (not shown) attached to the proximal ends (not shown) of the peripheral catheters is actuated. A fluid, such as a liquid, containing a bioactive material, such as a pharmaceutical material, is delivered under pressure to the catheter assembly **200** and thus into the patient's tissue. The fluid is delivered into the central lumens (not shown) of the associated peripheral catheters **214**. The fluid flows along the central lumens of the peripheral catheters **214** until it reaches the open ends of the distal end portions **234** of the peripheral catheters and is thereby introduced into the patient's tissue. When the patient's treatment is completed, the catheter assembly **200** may be removed by allowing the central catheter **212** to deflate and then withdrawing the catheter assembly from the patient's tissue.

Although the catheter assembly **200** of FIGS. **6-9** is illustrated and described as having its peripheral catheters **214** disposed outward of the outer surface **220** of its central catheter **212**, the peripheral catheters could be disposed, in whole or in part, in the wall **216** of the central catheter between the inner and outer surfaces **218** and **220**. With such a construction, the wall **216** could, in effect, be a sheath portion of the central catheter and could potentially replace the sheaths **292**.

FIGS. **10** through **12** illustrate a catheter assembly **300** that is constructed in accordance with a fourth example of the present invention. The catheter assembly **300** includes a first or central catheter **312** and second or peripheral catheters **314**, two of which are shown in FIGS. **10** and **11**. The central catheter **312** is made of a flexible and resilient biocompatible material, such as a medical grade silicone elastomer, and includes a longitudinally extending, tubular wall **316**. The tubular wall **316** includes a radially inner surface **318** and a radially outer surface **320**. Both the inner surface **318** and the outer surface **320** extend substantially the entire length of the central catheter **312**.

The inner surface **318** of the wall **316** defines a central lumen **322** that extends substantially the entire length of the central catheter **312**. The central lumen **322** is closed at the distal end **324** of the central catheter **312** by a thinned end portion **326** of the wall **316**. The central lumen **322** is open at the opposite, proximal end **328** of the central catheter **312**. The thinned end portion **326** of the wall **316** partially defines a balloon portion **329** of the central catheter **312** and the catheter assembly **300**. In the thinned end portion **326** of the wall **316**, the outer surface **320** of the wall **316** is separated from the inner surface **318** by a smaller distance than in a middle portion **321** of the length of the central catheter **312** and in a portion adjacent the proximal end **328** of the central catheter. As a consequence, the wall **316** has a greater thickness in the middle portion **321** of its length and adjacent its proximal end **328** than adjacent its distal end **324** and in the thinned end portion **326**.

The thinned end portion **326** of the wall **316** of the central catheter **312** is formed from a separate piece of flexible and resilient biocompatible material, such as a medical grade silicone elastomer, and is secured to the middle portion **321** of the wall by, for example, a biocompatible adhesive material or radio frequency welding. Alternatively, the thinned end portion **326** may be formed in one piece with the middle portion **321** of the wall **316**. The thinned end portion **326** of the wall **316** has a higher modulus of elasticity than the middle portion **321** of the length of the wall and the portion adjacent the proximal end **328** of the wall. As a result of the different moduli of elasticity and the previously described different thicknesses of the thinned end portion **326** and the middle portion **321** of the wall **316**, when the central lumen **322** of the central catheter **312** is subjected to increased fluid pressure, such as a pressure greater than ambient atmospheric pressure, the thinned end portion **326** of the wall **316** tends to distend or extend to a greater extent than, for example, the middle portion **321**.

As best shown in FIG. **10**A, tunnels or passages **330** are formed in the wall **316** of the central catheter **312** and extend generally lengthwise of the central catheter. Two passages **330** are shown in FIGS. **10** and **11** at diametrically opposite positions about the circumference of the wall **316**. The wall **316** of the central catheter **312** may include more or fewer such passages **330**, as desired. Each of the passages **330** is substantially identical in construction to the other passages **330**. Like the passages **130** of the catheter assembly **100** shown in FIGS. **4-5**, each of the passages **330** receives an associated peripheral catheter **314**. The peripheral catheters **314** are thus disposed in the wall **316** of the central catheter **312**, radially outward of the inner surface **318** of the wall **316** and, for a major portion of their lengths, radially inward of the outer surface **320** of the wall **316**. This portion of the lengths of the peripheral catheters **314** extends lengthwise substantially parallel to the central catheter **312**. As can be seen from FIG. **10**A, the outer diameter of each of the peripheral catheters **314** is smaller than the thickness of the middle portion **321** of the length of the wall **316** of the central catheter **312** and smaller than the diameter of the associated passage **330**. Each peripheral catheter **314** has a central lumen **332**, which is disposed outside of the central lumen **322** of the central catheter **312**. Likewise, the central lumen **322** of the central catheter **312** is disposed outside of the central lumens **332** of the peripheral catheters **314**. Each peripheral catheter **314** is formed of a biocompatible material, such as PTFE, that has sufficient rigidity to penetrate a patient's tissue and also has sufficient flexibility and resilience to withstand being deflected and then return to a non-deflected position.

As best seen in FIGS. **10** and **10**A, a distal end portion **334** of each peripheral catheter **314** can project radially outward of the outer surface **320** of the wall **316** of the central catheter **312** near the distal end **324** of the central catheter. To facilitate such radially outward projection of the peripheral catheter **314**, the passage **330** in the wall **316** of the central catheter **312** angles radially outward and opens onto the outer surface **320** of the wall **316**. The radially outward curvature of the passage **330** occurs adjacent the junction between the middle portion **321** of the wall **316** and the thinned end portion **326** of the wall. The distal end portion **334** of the peripheral catheter **314** is given a predetermined shape in the form of an outwardly directed curve or hook.

The proximal end portion **336** of each peripheral catheter **314** projects radially outward of the outer surface **320** of the wall **316** of the central catheter **312** near the proximal end **328** of the central catheter. The proximal end portion **336** of each peripheral catheter **314** is associated with a fluid inlet port or injection port assembly **380**, which receives the proximal end portion of its associated peripheral catheter.

Each injection port assembly **380** includes a sleeve portion **382** and connector portion **384**, such as a Luer lock connector. The sleeve portion **382** and connector portion **384** of each injection port assembly **380** are joined to one another and may be formed in one piece. The sleeve portion **382** of each injection port assembly **380** is elongated and extends between its associated connector portion **384** and an area on the outer surface **320** of the wall **316** of the central catheter **312** from which the proximal end portion **336** of the associated peripheral catheter **314** projects. The sleeve portion **382** surrounds and is bonded to the proximal end portion **336** of the associated peripheral catheter **314** and helps to protect the proximal end portion. The sleeve portion **382** is also adhesively bonded or otherwise secured to the outer surface **320** of the wall **316** of the central catheter **312**, thereby fixing the proximal end portion **336** of the associated peripheral catheter **314** to the wall **316** of the central catheter.

The proximal end portion **336** of each peripheral catheter **314** extends into the connector portion **384** of its associated injection port assembly **380**. The central lumen **332** of the peripheral catheter **314** communicates with a central lumen **386** in the connector portion **384** of the injection port assembly **380**. An outer surface **388** of the connector portion **384** is threaded to facilitate attachment of a second connector (not shown) and tubing (not shown) for delivering a fluid to the connector portion and thus to the peripheral catheter **314**. Such a fluid may flow along the central lumen **332** of the peripheral catheter **314** from its proximal end portion **336** into the distal end portion **334** of the peripheral catheter. The distal end of the peripheral catheter **314** is open so that fluid may flow out of the open distal end of the peripheral catheter.

The portion of the central catheter **312** adjacent the proximal end **328** is received in a tubular male connector **340**, such as a male Luer lock connector. The male connector **340** has a head portion **342** and an opposite threaded portion **344**. The head portion **342** of the male connector **340** has an outer surface **346** formed for manual manipulation to facilitate attachment of another connector (not shown), which, in turn, may be connected to and communicate with a length of tubing (not shown). The tubing delivers a fluid to the central lumen **322** for distending the thinned end portion **326** of the wall **316** of the central catheter **312** and inflating the central catheter. When distended, as shown in FIG. **10**, the thinned end portion **326** resembles a balloon and can occupy a space or volume that has a relatively large radial dimension. The central catheter **312** is thus suitable for use in a tissue cavity, such as a resection cavity from which a tumor has been surgically removed.

Distension of the thinned end portion **326** of the wall **316** of the central catheter **312** also deploys the distal end portions **334** of the peripheral catheters **314**. More specifically, as best shown in FIG. **12**, one or more elongated pieces of material, such as threads, **390** extend across and are secured to the outer surface **320** of the thinned end portion **326** of the wall **316**. The threads **390** are formed of a biocompatible material that has a lower modulus of elasticity than the thinned end portion **326** of the wall **316**. The threads **390** are thus less extensible than the thinned end portion **326** of the wall **316**, but are flexible. The material of which the threads **390** are formed may be any material that is biocompatible and that will produce threads that are less extensible than the thinned end portion **326** of the wall **316**, including, for example, plastic, silicone, metal, and fabric. The material of the threads **390** need not be twisted like yarn or plaited or woven. The threads **390** may be elongated bands or strips of material.

Each thread **390** is secured to at least one point on the outer surface **320** of the thinned end portion **326**, such as the distal end **324** of the central catheter **312**. The thread **390** then extends in a direction away from the distal end **324** of the central catheter **312** toward the middle portion **321** of the wall **316**. Near the middle portion **321** of the wall **316** of the central catheter **312** (when the central catheter is in a non-inflated or partially inflated condition, as, shown for example, in FIG. **11**), the thread **390** is connected at a junction **392** to at least one peripheral catheter **314**, thereby connecting the peripheral catheter **314** to the wall **316** of the central catheter. Each thread **390** may be secured to a single peripheral catheter **314**. Alternatively, as shown in FIG. **12**, each thread **390** may be secured at a first junction **392** to a first peripheral catheter **314**, extend to the distal end **324** of the central catheter **312** along a circumferential path on the outer surface **320** of the thinned end portion, and then extend back to a second junction **392** at which the thread is secured to a second peripheral catheter **314** positioned diametrically opposite the first peripheral catheter.

Because the thread or threads **390** are secured to the thinned end portion **326** of the wall **316** of the central catheter **312**, extension or distention of the thinned end portion **326** tends to pull the threads in a direction away from the middle portion **321** of the wall **316**. As the threads **390** are pulled away from the middle portion **321** of the wall **316**, the junctions **392** between the threads and the peripheral catheters **314**, together with the distal end portions **334** of the peripheral catheters, are similarly pulled in a direction away from the middle portion **321** of the wall. The curved or hooked distal end portions **334** of the peripheral catheters **314** are thereby deployed and pulled into the tissue surrounding the inflated or distended thinned end portion **326** of the wall **316**. Distension or extension of the thinned end portion **326** of the wall **316** thus causes the distal end portions **334** of the peripheral catheters to be pulled by the threads **390** from a first, non-deployed position or condition to a second, deployed position or condition.

To help determine the area in which the distal end portions **334** of the peripheral catheters **314** enter the surrounding tissue, a cover or sheath **394** is disposed over the outer surface **320** of the thinned end portion **326** of the wall **316**. As illustrated in FIG. **12**, the sheath **394** is generally semi-spherical in shape with a large diameter open end **396** disposed away from the middle portion **321** of the wall **316** and a small diameter end **397** disposed adjacent to the middle portion of the wall **316**. The small diameter end **397** of the sheath **394** is attached to the middle portion **321** of the wall **316** adjacent the junction between the middle portion and the thinned end portion **326** of the wall. The threads **390** and the distal end portions **334** of the peripheral catheters **314** extend between sheath **394** and the outer surface **320** of the thinned end portion **326** of the wall **316** of the central catheter **312**. The sheath **394** may have a greater or lesser surface area than shown in FIG. **12** and may, therefore, cover or overlap the thinned end portion **326** to a greater or lesser extent than shown in FIG. **12**.

The sheath **394** is formed of a material that has a lower modulus of elasticity than the material of which the thinned end portion **326** is made and tends to constrain the distal end portions **334** of the peripheral catheters **314**. As the thinned end portion **326** of the wall **316** is distended, the threads **390** and the distal end portions **334** of the peripheral catheters **314**

tend to be pulled from under the sheath **394** and may thus project away from the outer surface **320** of the wall **316** of the central catheter **312** and assume their outwardly curved, predetermined shape. As the distal end portions **334** of the peripheral catheters **314** assume their outwardly curved, predetermined shape, the peripheral catheters **314** penetrate the patient's tissue and extend into the patient's tissue away from the central catheter **312** in a radial array.

In use, the central catheter **312** of the catheter assembly **300** is introduced into a cavity, such as a resection cavity, in the tissue of a patient. The central catheter **312** is introduced into the tissue cavity in an uninflated or partially inflated condition, as shown in FIG. **11**, with the thinned end portion **326** of the wall **316** either not distended or partially distended. In this condition, the distal end portions **334** of the peripheral catheters **314** lie against the outer surface **320** of the thinned end portion **326** of the wall **316** of the central catheter **312** and are covered by the sheath **394**. When the central catheter **312** is appropriately positioned, fluid is introduced into the central lumen **322** of the central catheter to inflate or further inflate the central catheter and extend or distend the thinned end portion **326** of the wall **316** of the central catheter. As the central catheter **312** inflates, the thinned end portion **326** of the wall **316** of the central catheter resiliently stretches or distends. As the thinned end portion **326** of the wall **216** resiliently distends or extends, the central catheter **312** fills the cavity in the tissue of the patient and the distal end portions **334** of the peripheral catheters **314** are moved closer to the tissue surrounding and defining the cavity in the tissue.

In addition, as the central catheter **312** inflates and the wall **316** of the central catheter resiliently distends or extends, the threads **390** and the distal end portions **334** of the peripheral catheters **314** are pulled from under the sheath **394** so that the distal end portions **334** can project away from the outer surface **320** of the wall **316** and assume their outwardly curved, predetermined shape. As the distal end portions **334** of the peripheral catheters **314** assume their outwardly curved, predetermined shape, the peripheral catheters **314** penetrate the patient's tissue and extend into the patient's tissue away from the central catheter **312** in a radial array.

With the central and peripheral catheters **312** and **314** of the catheter assembly **300** appropriately positioned in the patient's tissue, therapeutic treatment of the tissue with a bioactive material can begin. To introduce the bioactive material, a pump or other device (not shown) connected to the tubing (not shown) attached to the injection port assemblies **380** of the peripheral catheters **314** is actuated. A fluid, such as a liquid, containing a bioactive material, such as a pharmaceutical material, is delivered under pressure to the catheter assembly **300** and thus into the patient's tissue. The fluid is delivered into the central lumens **332** of the associated peripheral catheters **314**. The fluid flows along the central lumens **332** of the peripheral catheters **314** until it reaches the open ends of the distal end portions **334** of the peripheral catheters and is thereby introduced into the patient's tissue.

When the patient's treatment is completed, the catheter assembly **300** may be removed by first allowing the central catheter **312** to deflate. To ensure that the peripheral catheters **314** are withdrawn from the patient's tissue and again covered by the sheath **394**, resilient devices **398**, such as elastic bands or springs, may be secured to the peripheral catheters in the middle portion **321** of the length of the wall **316** closer to the proximal end **328** than to the distal end **324** of the central catheter **312**. As shown in FIG. **10**, the resilient devices **398** may be stretched and flattened against the middle portion **321** of the wall **316** of the central catheter **312** when the thinned end portion **326** of the central catheter **312** is distended and the peripheral catheters **314** are exposed from beneath the sheath **394** and deployed. As shown in FIG. **11**, the resilient devices **398** return to a thicker, less stretched condition and the adjacent portions of their associated peripheral catheters **314** bow outward away from the central catheter **312** when the peripheral catheters are retracted and covered by the sheath **394**. To permit such outward bowing of the peripheral catheters **314**, the passages **330** in the wall **316** of the central catheter **312** must be at least partially open to the outer surface **320** of the wall **316** adjacent the resilient devices **398**. When the peripheral catheters **314** are withdrawn from the patient's tissue, the catheter assembly may be withdrawn from the cavity in the patient's tissue.

Although the peripheral catheters **314** are fixed, via the injection port assemblies **380**, to the wall **316** of the central catheter **312**, the peripheral catheters could be connected to the wall of the central catheter without being fixed to the wall. In particular, as the distal end portions **334** of the peripheral catheters **314** can be pulled away from the sheath **394** by the threads **390** in response to inflation of the central catheter **312**, the proximal end portions **336** of the peripheral catheters **314** could be longitudinally movable relative to the central catheter. In such a catheter assembly, the injection port assemblies would not be fixed to the wall **316** of the central catheter **312**, but rather would be movable along a portion of the length of the central catheter. The peripheral catheters **314** would remain connected to the wall **316** of the central catheter **312**, however, via the threads **390** and via the radial constraint imposed by the surfaces of the wall **316** defining the passages **330** through which the peripheral catheters extend. In addition, in such a catheter, the resilient devices **398** could be positioned adjacent the proximal end portions **336** of the peripheral catheters **314** so as to pull the peripheral catheters resiliently in a direction along the length of the central catheter **312** without outward bowing as the central catheter deflates and the thinned end portion **326** returns to a non-distended or less distended condition.

As another alternative, the individual threads **390** could be combined into a single member, such a cap having a partially spherical shape. Such a cap would be positioned at and attached to the distal end **324** of the central catheter **312** and would, therefore, be diametrically opposite the sheath **394** when the thinned end portion **326** of the central catheter is distended. The junctions **392** between the peripheral catheters **314** and such a cap could be at the edge of the cap that surrounds its larger diameter open end or at the ends of partial threads extending from the edge of the cap that surrounds its larger diameter open end. As a further alternative, the threads **390** could be relatively short pieces of material.

FIGS. **13** through **15**B illustrate a catheter assembly **400** that is constructed in accordance with a fifth example of the present invention. The catheter assembly **400** includes a first or central catheter **412** and second or peripheral catheters **414**, four of which are included in the catheter assembly and three of which are shown in FIGS. **13** and **14**. The central catheter **412** is made of a flexible and resilient biocompatible material, such as a medical grade silicone elastomer. As best seen in FIG. **14**A, the central catheter **412** includes a longitudinally extending, tubular wall **416**. The tubular wall **416** includes a radially inner surface **418** and a radially outer surface **420**. Both the inner surface **418** and the outer surface **420** extend substantially the entire length of the central catheter **412**.

The outer surface **420** of the wall **416** is separated from the inner surface **418** by a first distance in a first portion **419** of the length of the wall. The first portion **419** of the length of the wall **416** extends from a location adjacent to, but not including, the distal end **424** of the central catheter **412** toward the

proximal end **428** of the central catheter. The outer surface **420** of the wall **416** is separated from the inner surface **418** by a second distance, which is smaller than the first distance, in a second portion **421** of the length of the wall **416**. The second portion **421** of the length of the wall **416** extends from the first portion **419** to the proximal end **428** of the central catheter **412**. As a consequence of the difference between the first and second distances, the wall **416** has a greater thickness in the first portion **419** of its length than in the second portion **421**.

The first and second portions **419** and **421** of the length of the wall **416** of the central catheter **412** are formed of elastomeric materials having different properties. The elastomeric material in the first portion **419** of the length of the wall **416** has a relatively low durometer and a relatively low modulus of elasticity and, therefore, is relatively extensible. For example, the elastomeric material of the first portion **419** may have a Shore A hardness of from about 10 to about 20. The elastomeric material in the second portion **421** of the length of the wall **416** has a relatively high durometer and, for an elastomeric material, a relatively high modulus of elasticity and, therefore, is relatively inextensible. For example, the elastomeric material of the second portion **421** may have a Shore A hardness of from about 80 to about 90.

The first and second portions **419** and **421** of the wall **416** may be joined together by initially forming the second portion and then insert molding the first portion onto the second portion. A primer may be applied to the second portion **421** before the insert molding operation to enhance the strength of the joint between the second portion and the first portion **419**. To avoid an unnecessary increase in the outer diameter of the catheter assembly **400**, overmolding or overlapping of the material of the first portion **419** onto the outer surface **420** of the wall **416** of the second portion **421** may be prevented during the insert molding operation or, alternatively, overmolded or overlapping material may be removed from the outer surface of the second portion after the insert molding operation. As another alternative, the first and second portions **419** and **421** may be separately formed and then joined together end-to-end in a butt joint with a biocompatible adhesive.

The durometer of the first and second portions **419** and **421** can be adjusted using cross-linking agents and fillers. One possible filler is barium sulfate, which would provide radiopacity for the central catheter **412**. Optionally, a tether (not shown) formed of a flexible, non-ferrous material may be bonded or otherwise attached at one end to the first portion **419** of the wall **416** of the central catheter **412** and at an opposite end to the second portion **421** of the wall or another portion of the catheter assembly **400**. Such a tether (not shown) would help to ensure that the first portion **419** of the wall **416** is not completely disconnected from the remainder of the catheter assembly **400** if the joint between the first portion and the second portion **421** of the wall unexpectedly fails.

The inner surface **418** of the wall **416** defines a central lumen **422** that extends substantially the entire length of the central catheter **412**. The central lumen **422** is closed at the distal end **424** of the central catheter **412** by a plug **426** that is formed of a medical-grade elastomeric material and that is secured to the wall **416**. The elastomeric material of which the plug **426** is formed has a relatively high durometer and, for an elastomeric material, a relatively high modulus of elasticity and, therefore, is relatively inextensible. For example, a suitable elastomer for the plug **426** may have a Shore A hardness of from about 80 to about 90. Because the plug **426** is relatively inextensible and is secured to the wall **416**, the plug restricts or limits the extension or distension of the wall adjacent to the plug, even though the wall adjoining the plug is formed of relatively low durometer and, therefore, relatively extensible elastomeric material. Accordingly, the portion of the wall **416** adjoining or immediately adjacent to the plug **426**, including the distal end **424** of the central catheter **412**, is formed with an outer diameter equal to or less than the outer diameter of the first portion **419** of the wall, measured when the first portion of the wall is extended or distended as described below.

The plug **426** may be secured to the inner surface **418** of the wall **416** by a biocompatible adhesive (not shown). Alternatively, the plug **426** may be formed of a flowable and curable biocompatible material, such as a liquid silicone elastomer. The flowable and curable material is introduced into the central lumen **422** at the distal end **424** of the central catheter **412** and is cured in place so as to bond to the inner surface **418** of the wall **416**. A primer may be applied to the wall **416** before applying the adhesive or before introducing the flowable and curable material so as to enhance the strength of the joint between the plug **426** and the wall. An end surface of the plug **426** presented to the central lumen **422** may be shaped to provide a pocket to receive the end of a stylet **478**, as explained in more detail below. Opposite the plug **426**, at the proximal end **428** of the central catheter **412**, the central lumen **422** is open.

As shown in FIG. **14**A, tunnels or passages **430** are formed in the wall **416** of the central catheter **412** and extend generally lengthwise of the central catheter. Two passages **430** are shown in FIG. **14**A at diametrically opposite positions about the circumference of the wall **416**. The wall **416** of the central catheter **412** may include more or fewer such passages **430**, as desired. Each of the passages **430** is substantially identical in construction to the other passages **430**. Like the passages **130** of the catheter assembly **100** shown in FIGS. **4-5**, each of the passages **430** receives an associated peripheral catheter **414**. The peripheral catheters **414** are thus disposed in the wall **416** of the central catheter **412**, radially outward of the inner surface **418** of the wall **416** and, for a major portion of their lengths, radially inward of the outer surface **420** of the wall **416**. This major portion of the lengths of the peripheral catheters **414** extends lengthwise substantially parallel to the central catheter **412**.

Each peripheral catheter **414** has a central lumen **432**, which is disposed outside of the central lumen **422** of the central catheter. Likewise, the central lumen **422** of the central catheter **412** is disposed outside of the central lumens **432** of the peripheral catheters **414**. Each peripheral catheter **414** is formed of a biocompatible material, such as PTFE, that has sufficient rigidity to penetrate a patient's tissue and also has sufficient flexibility and resilience to withstand being deflected and then return to a non-deflected position.

As can be seen from FIG. **14**A, the outer diameter of each of the peripheral catheters **414** is smaller than the thickness of the wall **416** of the central catheter **412** and, at least in the first portion **419** of the length of the wall **416**, smaller than the diameter of the associated passage **430**. In the second portion **421** of the length of the wall **416**, the outer diameter of each of the peripheral catheters **414** may also be smaller than the diameter of the associated passage **430**. Alternatively, the outer diameter of each of the peripheral catheters **414** in the second portion **421** of the length of the wall **416** may be approximately the same as or slightly larger than the diameter of the associated passage **430** to provide an interference fit with the wall. Such an interference fit may result in the peripheral catheters **414** making the elastomeric material of the second portion **421** of the wall **416** less extensible (or more inextensible) if the peripheral catheters are made of a material

that is less extensible than the elastomeric material of the second portion. A similar effect on the extensibility of the second portion **421** of the length of the wall **416** may be achieved by forming additional passages in just the second portion and inserting lengths of peripheral catheter material or other flexible, relatively inextensible material into the additional passages and bonding the lengths of material to the wall.

As best seen in FIGS. **14** and **14**A, a distal end portion **434** of each peripheral catheter **414** can project radially outward of the outer surface **420** of the wall **416** of the central catheter **412** near the distal end **424** of the central catheter. To facilitate such radially outward projection of the peripheral catheter **414**, the distal end portion of each passage **430** in the wall **416** of the central catheter **412** curves or angles radially outward, as a departure ramp, and opens onto the outer surface **420** of the wall **416**. A short length of tubing, such as PTFE tubing, (not shown) may be positioned in the radially curved or angled portion of the passage **430** and bonded to the wall **416** to act as a bearing surface for sliding movement of the peripheral catheter **414** relative to the wall **416**. The distal end portion **434** of the peripheral catheter **414** has a predetermined shape in the form of a substantially straight line oriented at a relatively small angle to the remainder of the peripheral catheter, although other shapes, such as curved or hooked, may be used.

The proximal end **428** of the central catheter **412** and the proximal end portions **436** of the peripheral catheters **414** are connected to a hub **438**. The hub **438** is formed of plastic, although it may be formed of other materials. The hub **438** includes a main body portion **440**, a drive portion **442** that extends rearwardly or proximally (to the right as viewed in FIGS. **13** and **14**) from the main body portion, and four microcatheter sleeve portions **444** that project rearwardly and downwardly (as viewed in FIGS. **14** and **15**) from the main body portion. The proximal end **428** of the central catheter **412** is received in the main body portion **440** of the hub **438**. The outer surface **420** of the wall **416** of the central catheter **412** is bonded to an adjacent, circumferentially extending inner surface (not shown) of the main body portion **440**.

The peripheral catheters **414**, which are disposed in the wall **416** of the central catheter, are also received in the main body portion **440** of the hub **438**. The peripheral catheters **414** extend beyond the proximal end **428** of the central catheter **412** and into passages (not shown) formed in the main body portion **440** of the hub **438**. The passages (not shown) redirect the peripheral catheters **414** from a first orientation in which the peripheral catheters are disposed in an array circumferentially around the central lumen **422** of the central catheter **412** into a second orientation in which the peripheral catheters are arrayed on one side of the central catheter. From the main body portion **440** of the hub **438**, the passages (not shown) and the peripheral catheters **414** extend into the microcatheter sleeve portions **444** of the hub with one passage and its associated peripheral catheter being located in each microcatheter sleeve portion. Each peripheral catheter **414** extends out of its associated microcatheter sleeve portion **444** downwardly (as viewed in FIGS. **14** and **15**) away from the hub **438**. The proximal end portion **436** of each peripheral catheter **414** is associated with a fluid inlet port or injection port assembly **446**, which receives the proximal end portion of its associated peripheral catheter. Between the microcatheter sleeve portion **444** and the injection port assembly **446**, each peripheral catheter **414** is received inside a length of silicone tubing **445**, which helps to protect the peripheral catheter. The length of silicone tubing **445** is attached, by adhesive, for example, to the microcatheter sleeve portion **444** and to the injection port assembly **446** associated with the peripheral catheter **414**.

Each injection port assembly **446** includes a sleeve portion **448** and a connector portion **450**, such as a Luer lock connector. Although a female Luer lock connector may be used in the connector portion **450**, a male Luer lock connector or other atypical connector may alternatively be used to help prevent inadvertent connection of the injection port assembly **446** to commonly used fluid sources not intended for use with the catheter assembly **400**. The sleeve portion **448** and connector portion **450** of each injection port assembly **446** are joined to one another and may be formed in one piece. The sleeve portion **448** of each injection port assembly **446** is elongated and extends away from its associated connector portion **450** toward the hub **438**. The sleeve portion **448** surrounds and is bonded to the proximal end portion **436** of the associated peripheral catheter **414** and helps to protect the proximal end portion.

The proximal end portion **436** of each peripheral catheter **414** extends into the connector portion **450** of its associated injection port assembly **446**. The central lumen **432** of the peripheral catheter **414** communicates with a central lumen **452** in the connector portion **450** of the injection port assembly **446**. A surface (not shown) of the connector portion **450** is threaded to facilitate attachment of a second connector (not shown) and tubing (not shown) for delivering a fluid to the connector portion and thus to the peripheral catheter **414**. Such a fluid may flow along the central lumen **432** of the peripheral catheter **414** from its proximal end portion **436** into the distal end portion **434** of the peripheral catheter. The distal end of the peripheral catheter **414** is open so that fluid may flow out of the open distal end of the peripheral catheter.

As shown in FIGS. **15**A and **15**B, the drive portion **442** of the hub **438** is hollow and has a rectangular cross-section. An inner surface **454** of the drive portion **442** defines a lumen **456**, which is coaxial with and an extension of a corresponding lumen **458** in the main body portion **440** of the hub **438**. An outer surface **460** of the drive portion **442** is formed with rack teeth **462** that comprise the rack of a rack-and-pinion control mechanism or drive mechanism **464**.

The drive portion **442** of the hub **438** is shaped and dimensioned to be received in a stylet handle assembly **466**. The stylet handle assembly **466** and the catheter assembly **400** together form a catheter apparatus **401**. The stylet handle assembly **466** comprises a housing **468**, an end cover **470**, and a rotatable drive shaft **472**. The housing **468** is hollow and elongated. The housing **468** is also generally rectangular in cross-section with rounded corners to facilitate being grasped by a user of the stylet handle assembly **466**. Two spaced apart internal walls **474** extend lengthwise of the housing **468**. The proximal end **476** of the housing **468** is closed by an end wall (not shown) in which a small opening (not shown) is formed to receive the stylet **478**. The stylet **478** is formed of a metal alloy, such as 35N LT, and has a rounded distal end **480**. The 35N LT metal alloy, which is sold by Fort Wayne Metals Research Corp. of Fort Wayne, Ind., provides stiffness and also MRI compatibility as it is both non-magnetic and non-shadowing. When received in the opening (not shown) in the proximal end **476** of the housing **468**, the stylet **478** extends lengthwise of the housing between the internal walls **474**. The proximal end (not shown) of the stylet **478** is fixed to the housing **468** adjacent its proximal end **476**. The distal end **482** of the housing **468** is open and is formed with flexible fingers **484**.

The distal end **482** of the housing is closed by the end cover **470**, which has a generally cup-like shape. The end cover **470**

has an end wall **486** and a peripheral wall **488** that extends perpendicular to the end wall around the outer periphery of the end wall. An opening **490** is formed in the end wall **486** to receive the drive portion **442** of the hub **438**. Two spaced apart stub walls **492** extend away from the end wall **486** generally parallel to the peripheral wall **488** and are positioned so that the opening **490** is located between the stub walls. A portion of the peripheral wall **488** is formed with an inwardly projecting lip **489** that is complementary in shape to the fingers **484** on the distal end **482** of the housing **468**. The fingers **484** snap into mating engagement with the lip **489** to hold the end cover **470** on the housing **468**.

The rotatable drive shaft **472** is captured between the housing **468** and the end cover **470**. As best shown in FIG. **15**B, the rotatable drive shaft **472** includes a connecting shaft **496**. The connecting shaft **496** is captured between the housing **468** and the peripheral wall **488** of the end cover **470**. The connecting shaft **496** is also captured between the internal walls **474** of the housing **468** and the stub walls **492** of the end cover **470**. Adjacent one end of the connecting shaft **496** is a pinion gear **498**. The pinion gear **498** is positioned between the two internal walls **474** of the housing **468** and between the two stub walls **492** of the end cover **470**. At the opposite end of the connecting shaft **496** is a knurled knob **500**. The knurled knob **500** is disposed outside of the housing **468** to be grasped by a user of the stylet handle assembly **466**. The connecting shaft **496**, pinion gear **498**, and knurled knob **500** are formed in one piece from plastic, but may, alternatively, be formed of different materials and/or as separate components that are subsequently joined together.

When the drive portion **442** of the hub **438** is received in the opening **490** formed in the end cover **470**, the drive portion extends between the two stub walls **492** of the end cover and between the two internal walls **474** of the housing **468**. A tab **502** formed in the end wall **486** of the end cover **470** and projecting into the opening **490** fits into a complementary groove **504** in the drive portion **442** of the hub **438** to help align the drive portion and the stylet handle assembly. The rack teeth **462** formed on the outer surface **460** of the drive portion **442** engage the pinion gear **498** of the rotatable drive shaft **472**. Together, the pinion gear **498** and the rack teeth **462** form the rack-and-pinion control mechanism or drive mechanism **464**.

Knurled knob **500** of the rotatable drive shaft **472**, as can be seen in FIG. **15**B, is rotatable about an axis **506** that is oriented generally perpendicular to the longitudinal axis **508** of the stylet handle assembly **466**. Rotation of the knurled knob **500** by a user of the stylet handle assembly **466** produces rotation of the pinion gear **498** and resulting lengthwise movement of the drive portion **442** of the hub **438**. This lengthwise movement of the drive portion **442** of the hub **438** is movement relative to the stylet handle assembly **466** and relative to the stylet **478**, which is fixed to the housing **468** of the stylet handle assembly. The longitudinal or axial extent of the rack teeth **462** (e.g., the number of rack teeth and their spacing) on the drive portion **442** of the hub **438** can be selected to cause a desired amount of relative movement between the hub **438** and the stylet handle assembly **466**. As explained below, a desired amount of relative movement between the hub **438** and the stylet handle assembly **466** produces a desired amount of extension of the first portion **419** of the length of the wall **416**, a desired amount of reduction in the outer diameter of the first portion of the wall, and a desired amount of lengthwise deployment of the peripheral catheters **414**. The rack-and-pinion control mechanism or drive mechanism **464** is thus operable to produce controlled, relative movement between the hub **438** and the stylet **478** and controlled deployment of the peripheral catheters **414**.

As can be seen in FIGS. **14** and **15**, the second orientation of the peripheral catheters **414**, in which the peripheral catheters and their associated injection port assemblies **446** are all arrayed on one side of the central catheter **412**, as directed by the passages (not shown) in the main body portion **440** of the hub **438**, helps a user of the stylet handle assembly **466** to grasp and manipulate the stylet handle assembly. More particularly, having the peripheral catheters **414** and their associated injection port assemblies **446** on one side of the central catheter **412** and, therefore, on one side of the stylet handle assembly **466** permits a user of the stylet handle assembly to approach from other sides of the stylet handle assembly without having to maneuver around the peripheral catheters and injection port assemblies. Nonetheless, if desired, the peripheral catheters **414** could be maintained in their first orientation disposed in an array circumferentially around the central lumen **422** of the central catheter **412** as they are directed through the main body portion **440** and the microcatheter sleeve portions **444** of the hub **438**.

When the catheter assembly **400** is to be inserted into tissue, such as cerebral tissue, of a patient, stylet **478** is received in and engaged with the stylet handle assembly **466**. Specifically, the proximal end (not shown) of the stylet **478** is inserted into the opening **490** in the end cover **470** of the stylet handle assembly **466** and fixed in the opening (not shown) in the proximal end **476** of the housing **468** of the stylet handle assembly. The distal end **480** of the stylet **478** is inserted into and pushed lengthwise through the lumen **456** formed in the drive portion **442** of the hub **438**. The distal end **480** of the stylet **478** is then inserted into and pushed lengthwise through the lumen **458** formed in the main body portion **440** of the hub **438** and into the central lumen **422** of the central catheter **412**. As the distal end **480** of the stylet **478** approaches the distal end **424** of the central catheter, the drive portion **442** of the hub **438** of the catheter assembly **400** enters the stylet handle assembly **466** through the opening **490** in the end cover **470**. The drive portion **442** passes between the internal walls **474** of the housing **468**, and the rack teeth **462** on the drive portion engage the pinion gear **498** of the rotatable drive shaft **472** in the stylet handle assembly **466**.

At this point, the rounded distal end **480** of the stylet **478** is in contact with the plug **426** at the distal end **424** of the central catheter **412**. In particular, the rounded distal end **480** of the stylet **478** is received in the rounded pocket formed in the surface of the plug **426** presented to the central lumen **422** of the central catheter **412** such that the rounded distal end **480** and the rounded pocket help to center the stylet in the central lumen. Although the distal end **480** of the stylet **478** is shown as being rounded, the distal end could have a different shape, and the pocket formed in the surface of the plug **426** presented to the central lumen **422** of the central catheter **412** could also have a different, but complementary shape to help center the stylet in the central lumen. The first portion **419** of the length of the wall **416** is not yet extended, and the distal end portions **434** of the peripheral catheters **414** project from the first portion of the length of the wall, as shown in FIGS. **13** and **14**.

After the rounded distal end **480** of the stylet **478** contacts the plug **426** at the distal end **424** of the central catheter **412**, the user of the stylet handle assembly **466** grasps the stylet handle assembly and rotates the knurled knob **500**. Rotation of the knurled knob **500** causes the pinion gear **498** to engage successive rack teeth **462** on the drive portion **442** of the hub **438** and to draw the drive portion further into the stylet handle assembly **466**. As the drive portion **442** is drawn further into the stylet handle assembly **466**, the entire catheter assembly

400 is drawn toward the stylet handle assembly, and the stylet 478 is pressed against the plug 426 at the distal end 424 of the central catheter 412. Pressing the stylet 478 against the plug 426 causes the first portion 419 of the length of the wall 416 to extend or distend axially or lengthwise into a longitudinally extended condition.

The extension or stretching of the wall 416 occurs primarily in the thickened first portion 419 of the wall because the plug 426 is made of relatively inextensible material and is bonded to the inner surface 418 of the wall in the first portion and thereby effectively transfers the force applied by the stylet 478 to the wall in the first portion of its length. In addition, the first portion 419 of the length of the wall 416 is made of lower durometer and relatively more extensible material than the second portion 421 of the wall and thereby tends to extend or stretch in preference to the second portion of the length of the wall.

Extension or stretching of the first portion 419 of the length of the wall 416 causes the outer diameter of the wall to decrease or be reduced. This can be seen in FIGS. 14 and 15 by comparing the outer diameter of the first portion 419 in FIG. 14 with the outer diameter of the first portion in FIG. 15 and also by comparing the relative outer diameters of the first and second portions 419 and 421 in FIG. 14 with the relative outer diameters of the first and second portions in FIG. 15. The outer diameter of the first portion 419 of the wall 416 may be reduced to any desired extent, such as less than or equal to the outer diameter of the second portion 421 of the wall. Extension or stretching of the first portion 419 of the length of the wall 416 of the central catheter 412 also causes the first portion of the wall to be drawn over the distal end portions 434 of the peripheral catheters 414 or, in effect, causes the distal end portions of the peripheral catheters to be withdrawn into the passages 430 in the wall 416, as shown in FIG. 15. This result occurs because the peripheral catheters 414 are adhesively bonded to the surface of the wall 416 that defines the passage 430 adjacent the proximal end 428 of the central catheter or otherwise fixed against movement relative to the hub 438.

The durometers and thicknesses of the elastomeric materials used in the first and second portions 419 and 421 of the length of the wall 416 can be selected or tuned to provide a desired amount of reduction in the outer diameter of the first portion of the wall without excessive longitudinal extension of the first portion or use of excessive force. The durometers and thicknesses of the elastomeric materials used in the first and second portions 419 and 421 of the length of the wall 416 can also be selected or tuned to provide a desired extent to which the first portion of the wall is drawn over the distal end portions 434 of the peripheral catheters 414 without excessive longitudinal extension of the first portion. For example, if the distal end portions 434 of the peripheral catheters 414, when deployed, extend about 1 cm from the outer surface 420 of the wall 416 of the central catheter, the longitudinal extension of the first portion 419 of the length of the wall 416 should also be about 1 cm to cover the distal end portions of the peripheral catheters completely without excess extension of the wall beyond the extension necessary to cover the distal end portions of the peripheral catheters. Such an extension of the first portion 419 of the wall 416 should also produce a corresponding reduction in the outer diameter of the first portion of the wall so that the outer diameter of the first portion is equal to or less than the outer diameter of the second portion 421 of the length of the wall. By way of example, in an embodiment in which the first portion 419 of the wall 416 has a length of 2.30 cm, an outer diameter of 3.00 mm, and a central lumen having a diameter of 0.79 mm, the outer diameter of the first portion can be reduced by about 0.50 mm by extending the sample lengthwise to about 1.50 times (150% of) its non-extended length.

As they are being covered by the wall 416 of the first portion 419 of the length of the central catheter 412 or, in effect, withdrawn into the passages 430, the distal end portions 434 of the peripheral catheters 414 are deflected from their outwardly directed, predetermined shape and are constrained in a generally straight configuration by the wall of the central catheter. When the peripheral catheters 414 have been fully withdrawn or retracted into the wall 416 of the central catheter 412, the outer surface 420 of the wall 416 of the central catheter appears essentially smooth and uninterrupted. The wall 416 of the central catheter 412 thus functions as a sheath portion of the central catheter and covers the distal end portions 434 of the peripheral catheters 414.

When the stylet 478 reaches the end of its stroke, as determined by the pinion gear 498 engaging the last tooth 462 on the drive portion 442 of the hub 438 and/or by contact between the main body portion 440 of the hub 438 and the end cover 470 of the stylet handle assembly 466, as shown in FIG. 15, the stylet may be secured in place to facilitate coordinated manipulation of the stylet and the catheter assembly 400. As shown in FIG. 15B, the stylet 478 may be secured in place by locking the stylet handle assembly 466, to which the stylet is secured, to the hub 438 to which the central catheter 412 is secured. Specifically, a projecting detent feature 510 is formed on the drive portion 442 of the hub 438 adjacent the main body portion 440 of the hub, and a complementary projecting detent feature 512 is formed on the end wall 486 of the end cover 470 of the stylet handle assembly 466 adjacent the opening 490 in the end cover. The detent features 510 and 512 engage one another to secure the catheter assembly 400 to the stylet handle assembly 466.

The detent features 510 and 512 may engage with an audible click or a haptically perceptible motion to indicate to the user of the stylet handle assembly 466 that the stylet 478 has come to the end of its stroke. Similarly, the detent features 510 and 512 may disengage with an audible click or a haptically perceptible motion to indicate to the user of the stylet handle assembly 466 that relative movement between the stylet 478 and the catheter assembly 400 has begun. The surfaces of the detent features 510 and 512 that initially engage one another as the catheter assembly 400 is drawn toward the stylet handle assembly 466 may also be formed as inclined ramps to facilitate movement of the detent features past each other into a locking position. Interengagement of the detent features 510 and 512 can help prevent inadvertent relative longitudinal movement between the stylet handle assembly 466 and the catheter assembly 400.

When the stylet handle assembly 466 is secured to the hub 438, the stylet 478 and the catheter assembly 400 tend to move more consistently as a single unit and can be manipulated more easily and accurately. In particular, the stylet 478 can then be used to insert the extended central catheter 412 and the peripheral catheters 414 into the tissue of a patient. Because the outer diameter of the first portion 419 of the wall 416 of the central catheter 412 has been reduced due to the lengthwise extension or distension of the first portion, the opening formed in the patient's tissue is smaller than it would be otherwise. Because the distal end portions 434 of the peripheral catheters 414 have been withdrawn into the wall 416 of the central catheter, the peripheral catheters do not interfere with the insertion of the central catheter into the patient's tissue.

When the distal end 424 of the central catheter 412 is appropriately positioned in a patient's tissue, the stylet handle

assembly **466** is held so as to maintain the distal end of the central catheter in position. The knurled knob **500** of the rotatable drive shaft **472** can then be rotated in a direction to disengage the detent features **510** and **512** and to cause relative movement between (a) the catheter assembly **400** and (b) the stylet handle assembly **466** and the stylet **478**. In particular, the hub **438** of the catheter assembly **400** is moved in a direction away from the stylet handle assembly **466**. As the hub **438** is moved away from the stylet handle assembly **466**, the resilience of the extended first portion **419** of the wall **416** of the central catheter **412** pulls the proximal end **428** of the central catheter toward the distal end **424** of the central catheter. The central catheter **412** thus returns resiliently to its initial, non-extended length, as shown in FIGS. **13** and **14**.

When the central catheter **412** resiliently returns to its initial, non-extended length and the wall **416** of the central catheter likewise resiliently returns from its longitudinally extended condition to its initial, non-extended length, the distal end portions **434** of the peripheral catheters **414** are no longer withdrawn into the wall **416**. The distal end portions **434** of the peripheral catheters **414** instead project from the outer surface **420** of the wall **416** of the central catheter and assume their outwardly directed, predetermined shape. As the distal end portions **434** of the peripheral catheters **414** assume their outwardly directed, predetermined shape, the peripheral catheters **414** penetrate the patient's tissue and extend into the patient's tissue away from the central catheter **412** in a radial array. In addition, as the wall **416** of the central catheter **412** resiliently returns to its initial length, the outer diameter of the wall, particularly the first portion **419**, increases from its reduced condition back to its original dimension. The increase in the outer diameter of the wall **416** of the central catheter **412** causes the outer surface **420** of the first portion **419** of the wall **416** to press tightly against adjacent surfaces of the patient's tissue. The resulting close fit between the outer surface **420** of the wall **416** and the adjacent surfaces of the patient's tissue helps to prevent fluid introduced into the tissue by the peripheral catheters **414** from flowing back along the outer surface of the wall toward the proximal end **428** of the central catheter **412**.

With the central and peripheral catheters **412** and **414** of the catheter assembly **400** appropriately positioned in the patient's tissue, therapeutic treatment of the tissue with a bioactive material can begin. To introduce the bioactive material, the threaded surface (not shown) of the connector portion **450** of each injection port assembly **446** is connected with a connector (not shown) and the distal end of a length of tubing (not shown). A proximal end (not shown) of the tubing is attached to a device (not shown), such as a pump, for delivering a fluid, such as a liquid. The fluid contains a bioactive material, such as a pharmaceutical material, and is delivered from the tubing into the central lumen **452** of the connector portion **450** of the injection port assembly **446** and then into the central lumen **432** of the associated peripheral catheter **414**. The fluid flows along the central lumen **432** of the peripheral catheter **414** until it reaches the open end of the distal end portion **434** of the peripheral catheter and is thereby introduced into the patient's tissue.

If the patient's treatment is continued over an extended period of time and the catheter assembly **400** is therefore left implanted in the patient's tissue for an extended period of time, the stylet handle assembly **466** may be disengaged from the hub **438** of the catheter assembly, and the stylet may thereby be withdrawn entirely from the catheter assembly. Disengagement of the stylet handle assembly **466** and withdrawal of the stylet **478** from the catheter assembly **400** will leave open the proximal end of the lumen **456** in the drive portion **442** of the hub **438**. Because the lumen **456** communicates, via the lumen **458** in the main body portion **440** of the hub **438**, with the central lumen **422** of the central catheter **412**, a cover (not shown) may be placed over the proximal end of the drive portion **442** to keep foreign materials from entering the proximal end **428** of the central lumen in the central catheter. Such a cover (not shown) may also extend over the rack teeth **462** on the outer surface **460** of the drive portion **442** to help protect the rack teeth against damage.

When the patient's treatment is completed, the catheter assembly **400** may be removed by reintroducing the stylet **478** into the catheter assembly to extend or distend the central catheter **412**. If the stylet handle assembly **466** has been disengaged from the catheter assembly **400**, the stylet is reinserted into the lumen **456** in the drive portion **442** of the hub **438**. As the stylet **478** is moved into and through the central lumen **422** of the central catheter **412**, the drive portion **442** of the hub **438** of the catheter assembly **400** enters the stylet handle assembly **466** through the opening **490** in the end cover **470**. When the rack teeth **462** on the drive portion **442** engage the pinion gear **498** of the rotatable drive shaft **472** in the stylet handle assembly **466**, the knurled knob **500** can be rotated to draw the hub **438** of the catheter assembly **400** closer to the stylet handle assembly **466** and to press the rounded distal end **480** of the catheter against the plug **426** at the distal end **424** of the central catheter **412**.

Pressing the stylet **478** against the plug **426** as the hub **438** of the catheter assembly **400** is drawn closer to the stylet handle assembly **466** causes the first portion **419** of the length of the wall **416** to extend or distend axially or lengthwise into a longitudinally extended condition and effectively causes the distal end portions **434** of the peripheral catheters **414** to be withdrawn into the passages **430** in the wall **416**. When the peripheral catheters **414** have been fully withdrawn or retracted into the wall **416** of the central catheter **412**, the stylet handle assembly **466** can be moved away from the patient, thereby withdrawing the catheter assembly **400** from the patient's tissue.

While the stylet handle assembly **466** of FIGS. **13-15** incorporates a pinion gear **498** to engage rack teeth **462** formed on the drive portion **442** of the hub **438** of the catheter assembly **400**, thereby forming a rack-and-pinion drive mechanism **464**, other mechanisms may be employed for controlled deployment of the peripheral catheters **414**. For example, FIG. **16** illustrates an alternative lead screw control mechanism or drive mechanism **520** that may be substituted for the rack-and-pinion drive mechanism **464** of FIGS. **13-15**. To employ the lead screw drive mechanism **520**, the drive portion **442** of the hub **438** no longer includes rack teeth **462** but rather includes a lead screw defined by a screw thread **522** that encircles a cylindrical outer surface of the drive portion. Similarly, the pinion gear **498** of the rotatable drive shaft **472** of the stylet handle assembly **466** is replaced with a threaded nut **524** that encircles the drive portion **442**.

The threaded nut **524** has a knurled outer surface **526** that can be grasped by a user of the stylet handle assembly **466** and a threaded inner surface **528** that engages and rides on the screw thread **522** of the drive portion **442** of the hub **438**. The threaded nut **524** is thus rotated about an axis **530** that is parallel to or coaxial with the longitudinal axis **508** of the stylet handle assembly, whereas the knurled knob **500** of the rotatable drive mechanism is rotated about an axis **506** that is oriented generally perpendicular to the longitudinal axis **508** of the stylet handle assembly **466**. Rotation of the threaded nut **524** causes the drive portion **442** of the hub **438** to move longitudinally without rotating. As with the longitudinal extent of the rack teeth **462**, the axial or longitudinal extent of

the screw thread **522** can be selected to cause a desired amount of extension of the first portion **419** of the length of the wall **416** and a desired amount of lengthwise deployment of the peripheral catheters **414**. The lead screw control mechanism or drive mechanism **520** is thus operable to produce controlled, relative movement between the hub **438** and the stylet **478** and controlled deployment of the peripheral catheters **414**.

Although the hub **438** of the catheter assembly **400** shown in FIG. **16** includes the screw thread **522** forming the lead screw of the lead screw drive mechanism **520** and the stylet handle assembly **466** includes the threaded nut **524** of the lead screw drive mechanism, the catheter assembly could alternatively include the nut and the stylet handle assembly could include the screw thread defining the lead screw. Likewise, while the hub **438** of the catheter assembly **400** shown in FIGS. **13-15** includes the rack teeth **462** forming the rack of the rack-and-pinion drive mechanism **464** and the stylet handle assembly includes the pinion gear **498**, the catheter assembly could alternatively include the pinion gear and the stylet handle assembly could include the rack teeth.

The stylet handle assembly **466** may optionally include a window or transparent portion **540**, as shown in phantom in FIG. **13**, to allow a user of the stylet handle assembly to see the movement of the drive portion **442** of the hub **438** relative to the stylet handle assembly. Use of such a window **540** may be enhanced by having hash marks or other indicia **542** on an upper surface of the drive portion **442** of the hub **438** to indicate more precisely the extent of the relative movement.

FIG. **17** illustrates an alternative configuration for the wall **416** of the central catheter **412** and, more particularly, for the second portion **421** of the length of the wall. As shown, the outer surface **420** of the wall **416** is formed with troughs or grooves **550** that extend lengthwise of the central catheter **412**. The grooves **550** are configured and dimensioned to receive the peripheral catheters **414**. Use of such grooves **550** can facilitate assembly of the peripheral catheters **414** in the less extensible, higher durometer second portion **421** of the length of the wall **416** as the peripheral catheters may be pressed into place radially from a position adjacent and parallel to the central catheter **412**.

In addition, use of the grooves **550** can permit the diameter of the central lumen **422** of the central catheter **412** to be increased as compared to the diameter of the central lumen in the central catheter when the peripheral catheters **414** are disposed in the wall **416** of the central catheter. Specifically, for certain elastomeric materials, such as medical grade silicone elastomer, a minimum wall thickness should be provided to ensure structural integrity of the wall. If, for example, a peripheral catheter **414** is disposed in the wall **416** of a central catheter **412** formed of medical grade silicone elastomer, the minimum wall thickness should be provided both radially inward and radially outward of the peripheral catheter. If, on the other hand, the peripheral catheter **414** is disposed in a groove **550** in the radially outer surface **420** of the wall **416**, the minimum wall thickness need only be provided between the bottom of the groove and the radially inner surface **418** of the wall. As a result, for any given outer diameter of a central catheter **412**, the diameter of the central lumen **422** can be larger than if the peripheral catheter **414** were incorporated in the wall **416**. A larger diameter for the central catheter **422** can permit the use of a larger diameter stylet and/or provide a greater clearance between the outer surface of the stylet and the radially inner surface **418** of the wall **416** of the central catheter.

FIGS. **18** and **19** illustrate a catheter assembly **600** that is constructed in accordance with a sixth example of the present invention. The catheter assembly **600** includes a first or central catheter **612** and second or peripheral catheters **614**, four of which are included in the catheter assembly. The central catheter **612** is made of a flexible and resilient biocompatible material, such as a medical grade silicone elastomer. As best seen in FIG. **19**, the central catheter **612** includes a longitudinally extending, tubular wall **616**. The tubular wall **616** includes a radially inner surface **618** and a radially outer surface **620**. Both the inner surface **618** and the outer surface **620** extend substantially the entire length of the central catheter **612**.

The outer surface **620** of the wall **616** is separated from the inner surface **618** by a first distance in a first portion **619** of the length of the wall. The first portion **619** of the length of the wall **616** extends from a location adjacent to, but not including, the distal end **624** of the central catheter **612** toward the proximal end **628** of the central catheter. The outer surface **620** of the wall **616** is separated from the inner surface **618** by a second distance, which is smaller than the first distance, in a second portion **621** of the length of the wall **616**. The second portion **621** of the length of the wall **616** extends from the first portion **619** to the proximal end **628** of the central catheter **612**. As a consequence of the difference between the first and second distances, the wall **616** has a greater thickness in the first portion **619** of its length than in the second portion **621**.

The first and second portions **619** and **621** of the length of the wall **616** of the central catheter **612** are formed of elastomeric materials having different properties. The elastomeric material in the first portion **619** of the length of the wall **616** has a relatively low durometer and a relatively low modulus of elasticity and, therefore, is relatively extensible. For example, the elastomeric material of the first portion **619** may have a Shore A hardness of from about 10 to about 50, preferably from about 20 to about 40. The elastomeric material in the second portion **621** of the length of the wall **616** has a relatively high durometer and, for an elastomeric material, a relatively high modulus of elasticity and, therefore, is relatively inextensible. For example, the elastomeric material of the second portion **621** may have a Shore A hardness of from about 80 to about 90.

The first and second portions **619** and **621** of the wall **616** may be joined together by initially forming the second portion and then insert molding the first portion onto the second portion. A primer may be applied to the second portion **621** before the insert molding operation to enhance the strength of the joint between the second portion and the first portion **619**. To avoid an unnecessary increase in the outer diameter of the catheter assembly **600**, overmolding or overlapping of the material of the first portion **619** onto the outer surface **620** of the wall **616** of the second portion **621** may be prevented during the insert molding operation or, alternatively, overmolded or overlapping material may be removed from the outer surface of the second portion after the insert molding operation. As another alternative, the first and second portions **619** and **621** may be separately formed and then joined together end-to-end in a butt joint with a biocompatible adhesive.

The durometer of the first and second portions **619** and **621** can be adjusted using cross-linking agents and fillers. One possible filler is barium sulfate, which would provide radiopacity for the central catheter **612**. Optionally, a tether (not shown) formed of a flexible, non-ferrous material may be bonded or otherwise attached at one end to the first portion **619** of the wall **616** of the central catheter **612** and at an opposite end to the second portion **621** of the wall or another portion of the catheter assembly **600**. Such a tether (not shown) would help to ensure that the first portion **619** of the

wall **616** is not completely disconnected from the remainder of the catheter assembly **600** if the joint between the first portion and the second portion **621** of the wall unexpectedly fails.

The inner surface **618** of the wall **616** defines a central lumen **622** that extends substantially the entire length of the central catheter **612**. The central lumen **622** is closed at the distal end **624** of the central catheter **612** by a plug **626** that is formed of a medical-grade elastomeric material and that is secured to the wall **616**. The elastomeric material of which the plug **626** is formed has a relatively high durometer and, for an elastomeric material, a relatively high modulus of elasticity and, therefore, is relatively inextensible. For example, a suitable elastomer for the plug **626** may have a Shore A hardness of from about 80 to about 90. Because the plug **626** is relatively inextensible and is secured to the wall **616**, the plug helps to restrict or limit the extension or distension of the wall adjacent to the plug, even though the wall adjoining the plug is formed of relatively low durometer and, therefore, relatively extensible elastomeric material. Accordingly, the portion of the wall **616** adjoining or immediately adjacent to the plug **626**, including the distal end **624** of the central catheter **612**, is formed with an outer diameter that is (a) less than the outer diameter of the first portion **619** of the wall when the first portion is not distended and (b) also equal to or less than the outer diameter of the first portion **619** of the wall when the first portion of the wall is extended or distended as described below.

To help further restrict or limit the extension or distension of the wall adjacent to the plug **626**, a cup-shaped cap **627** is positioned in the central lumen of the central catheter **612** adjacent to the plug. The cup-shaped cap **627** has a closed end portion **629** that is relatively thick. The closed end portion **629** of the cup-shaped cap **627**, like the plug **626**, is located beyond the first portion **619** of the wall **616** in a distal direction. The material of which the cap **627** is formed has a higher durometer and a higher modulus of elasticity than the elastomeric material of which the plug **626** is formed. For example, a suitable material for the cap **627** may be polyether ether ketone (PEEK), which may have a Shore D hardness of about 80. Because the cap **627** is relatively inextensible and is secured to the wall **616**, the cap further restricts or limits the extension or distension of the wall adjacent to the plug **626** and the cap.

The plug **626** and the cap **627** may be fabricated outside of the central catheter **612** and then inserted into the central lumen **622** and secured to the inner surface **618** of the wall **616** by a biocompatible adhesive (not shown). Alternatively, the plug **626**, at least, may be formed of a flowable and curable biocompatible material, such as a liquid silicone elastomer. The flowable and curable material is introduced into the central lumen **622** at the distal end **624** of the central catheter **612** and is cured in place so as to bond to the inner surface **618** of the wall **616**. A primer may be applied to the wall **616** before applying the adhesive or before introducing the flowable and curable material so as to enhance the strength of the joint between the plug **626** and the wall. An end surface of the plug **626** presented toward the central lumen **622** contacts the closed end portion **629** of the cup-shaped cap **627**. The open end of cup-shaped cap **627** is, in turn, presented to the central lumen **622** to receive the end of a stylet **678**, as explained in more detail below. Opposite the plug **626**, at the proximal end **628** of the central catheter **612**, the central lumen **622** is open.

As shown in FIG. **19**, tunnels or passages **630** are formed in the wall **616** of the central catheter **612** and extend generally lengthwise of the central catheter. Two passages **630** are shown in FIG. **19** at diametrically opposite positions about the circumference of the wall **616**. The wall **616** of the central catheter **612** includes four such passages **630**, but may include more or fewer such passages **630**, as desired. Each of the passages **630** is substantially identical in construction to the other passages **630**. Like the passages **130** of the catheter assembly **100** shown in FIGS. **4-5**, each of the passages **630** receives an associated peripheral catheter **614**. The peripheral catheters **614** are thus disposed in the wall **616** of the central catheter **612**, radially outward of the inner surface **618** of the wall **616** and, for a major portion of their lengths, radially inward of the outer surface **620** of the wall **616**. This major portion of the lengths of the peripheral catheters **614** extends lengthwise substantially parallel to the central catheter **612**.

Each peripheral catheter **614** has a central lumen **632**, which is disposed outside of the central lumen **622** of the central catheter. Likewise, the central lumen **622** of the central catheter **612** is disposed outside of the central lumens **632** of the peripheral catheters **614**. Each peripheral catheter **614** is formed of a biocompatible material, such as PTFE, that has sufficient rigidity to penetrate a patient's tissue and also has sufficient flexibility and resilience to withstand being deflected and then return to a non-deflected position.

As can be seen from FIG. **19**, the outer diameter of each of the peripheral catheters **614** is smaller than the thickness of the wall **616** of the central catheter **612** and, at least in the first portion **619** of the length of the wall **616**, smaller than the diameter of the associated passage **630**. In the second portion **621** of the length of the wall **616**, the outer diameter of each of the peripheral catheters **614** may also be smaller than the diameter of the associated passage **630**. Alternatively, the outer diameter of each of the peripheral catheters **614** in the second portion **621** of the length of the wall **616** may be approximately the same as or slightly larger than the diameter of the associated passage **630** to provide an interference fit with the wall. Such an interference fit may result in the peripheral catheters **614** making the elastomeric material of the second portion **621** of the wall **616** less extensible (or more inextensible) if the peripheral catheters are made of a material that is less extensible than the elastomeric material of the second portion. A similar effect on the extensibility of the second portion **621** of the length of the wall **616** may be achieved by adhesively bonding the peripheral catheters **614** to the surface of the wall that defines the passages **630** in the second portion of the length of the wall. The extensibility of the second portion **621** of the length of the wall **616** may also be similarly affected by forming additional passages in just the second portion and inserting lengths of peripheral catheter material or other flexible, relatively inextensible material into the additional passages and bonding the lengths of material to the wall.

A distal end portion **634** of each peripheral catheter **614** can project radially outward of the outer surface **620** of the wall **616** of the central catheter **612** near the distal end **624** of the central catheter. To facilitate such radially outward projection of the peripheral catheter **614**, the distal end portion of each passage **630** in the wall **616** of the central catheter **612** curves or angles radially outward, as a departure ramp, and opens onto the outer surface **620** of the wall **616**. The point at which each passage **630** opens onto the outer surface **620** is located in the portion of the wall **616** immediately adjacent to the plug **626** and the cap **627** and beyond the first portion **619** of the wall **616** in a distal direction. A short length of tubing, such as PTFE tubing, (not shown) may be positioned in the radially curved or angled portion of the passage **630** and bonded to the wall **616** to act as a bearing surface for sliding movement of the peripheral catheter **614** relative to the wall **616**. The distal end portion **634** of the peripheral catheter **614** has a predeter-

mined shape in the form of an outwardly directed curve or hook, although other shapes, such as a substantially straight line oriented at a relatively small angle to the remainder of the peripheral catheter, may be used.

The proximal end **628** of the central catheter **612** and the proximal end portions **636** of the peripheral catheters **614** are connected to a hub **638**. The hub **638** is formed of plastic, although it may be formed of other materials. The hub **638** includes a main body portion **640** and a cover portion **642** that extends rearwardly or proximally (to the right as viewed in FIG. **18**) from the main body portion. The main body portion **640** has an elongated tubular shape with an open distal end and an open proximal end. The proximal end **628** of the central catheter **612** is received in the open distal end of the main body portion **640** of the hub **638**. Inside the main body portion **640** is a bushing (not shown). The outer surface **620** of the wall **616** of the central catheter **612** is bonded to an adjacent, circumferentially extending inner surface (not shown) of the bushing (not shown).

The peripheral catheters **614**, which are disposed in the wall **616** of the central catheter, are also received in the main body portion **640** of the hub **638**. The peripheral catheters **614** extend into the bushing (not shown) in the main body portion **640** and beyond the proximal end **628** of the central catheter **612**. Within the bushing (not shown), the peripheral catheters **614** are received in passageways (not shown) and are adhesively bonded to adjacent inner surfaces (not shown) of the bushing (not shown) that define the passageways. The peripheral catheters **614** then extend out of and proximally beyond the bushing and are received in grooves (not shown) formed in the bottom (as viewed in FIG. **18**) of the main body portion **640** of the hub **638**. In the course of traversing the space within the main body portion **640** between the bushing (not shown) and the grooves (not shown), the peripheral catheters **614** are redirected from a first orientation in which the peripheral catheters are disposed in an array circumferentially around the central lumen **622** of the central catheter **612** into a second orientation in which the peripheral catheters are arrayed on one side of the central catheter.

After being redirected into the second orientation in which it is arrayed on one side of the central catheter **612**, each peripheral catheter **614** extends out of the proximal end of the main body portion **640** of the hub **638** downwardly (as viewed in FIG. **18**) away from the hub. The proximal end portion **636** of each peripheral catheter **614** is associated with a fluid inlet port or injection port assembly **646**, which receives the proximal end portion of its associated peripheral catheter. Between the main body portion **640** of the hub **638** and the injection port assembly **646**, each peripheral catheter **614** is received inside a length of silicone tubing **648**, which helps to protect the peripheral catheter. The length of silicone tubing **648** is attached, by adhesive, for example, to the injection port assembly **646** associated with the peripheral catheter **614**.

Each injection port assembly **646** includes a connector portion **650**, such as a Luer lock connector. Although a female Luer lock connector may be used in the connector portion **650**, a male Luer lock connector or other atypical connector may alternatively be used to help prevent inadvertent connection of the injection port assembly **646** to commonly used fluid sources not intended for use with the catheter assembly **600**. The central lumen **632** of the peripheral catheter **614** communicates with a central lumen **652** in the connector portion **650** of the injection port assembly **646**. A surface (not shown) of the connector portion **650** is threaded to facilitate attachment of a second connector (not shown) and tubing (not shown) for delivering a fluid to the connector portion and thus to the peripheral catheter **614**. Such a fluid may flow along the central lumen **632** of the peripheral catheter **614** from its proximal end portion **636** into the distal end portion **634** of the peripheral catheter. The distal end of the peripheral catheter **614** is open so that fluid may flow out of the open distal end of the peripheral catheter.

The cover portion **642** of the hub **638** includes a closure **653** and a latch **654**. The closure **653** is shaped to close a significant part of the open proximal end of the main body portion **640** of the hub **638**. With the cover portion **642** and closure **653** in place, the only part of the open proximal end of the main body portion **640** that remains open is a part that permits the peripheral catheters **614** to extend out of the main body portion. The latch **654** has an elongated tubular shape and extends away from the closure **653** in a proximal direction (to the right, as viewed in FIG. **18**). The latch is generally rectangular in cross-section with rounded corners. An inner surface of the latch **654** and the cover portion **642** defines a lumen **656**, which is coaxial with the central lumen **622** in the central catheter **612**. An outer surface **660** of the latch **654** of the cover portion **642** is formed with two outwardly projecting teeth **662** disposed adjacent to, but spaced from the closure **653**. The teeth **662** comprise a part of a control mechanism **664**.

The latch **654** of the cover portion **642** of the hub **638** is shaped and dimensioned to be received in a stylet handle assembly **666**. The stylet handle assembly **666** and the catheter assembly **600** together form a catheter apparatus **601**. The stylet handle assembly **666** comprises a housing **668**, a handle **670**, and two arms **672**. The housing **668**, the handle **670**, and the arms **672** are formed in one piece from a polymeric material, although they may be formed of other materials.

The housing **668** is hollow and elongated. The housing **668** is also generally rectangular in cross-section with rounded corners. The internal shape of the housing **668** is substantially the same as the external shape of the latch **654**, excluding the teeth **662**. The internal dimensions of the housing **668** are slightly larger than the external dimensions of the latch **654**. The distal end **674** of the housing **668** is open. Consequently, the housing **668** is able to receive the portion of the latch **654** that is proximal of the teeth **662**.

The proximal end **676** of the housing **668** is also open, but mates with and is closed by the handle **670**. The handle **670** includes a tubular central body **680** and two laterally extending wings **682**. The laterally extending wings **682** both lie in the same plane and include raised ribs **684** to facilitate the handle **670** being gripped by a user of the stylet handle assembly **666**. The tubular central body **680** includes a central lumen (not shown) that is formed to receive the stylet **678**. The stylet **678** is formed of a metal alloy, such as 35N LT, and has a rounded distal end (not shown). The 35N LT metal alloy, which is sold by Fort Wayne Metals Research Corp. of Fort Wayne, Ind., provides stiffness and also MRI compatibility as it is both non-magnetic and non-shadowing. When received in the central lumen (not shown) in the tubular central body **680** of the handle **670**, the stylet **678** extends lengthwise of both the handle **670** and the housing **668**. The proximal end (not shown) of the stylet **678** is fixed to the handle **670** adjacent its proximal end.

The arms **672** of the stylet handle assembly **666** extend laterally from opposite sides of the exterior of the housing **668**. Each arm **672** has a curved portion **686**, a straight portion **688**, and a hook portion **690**. The curved portion **686** of each arm **672** is attached at one end to the housing **668**. The curved portion **686** of each arm **672** extends in a proximal direction away from the exterior of the housing **668**. The end of the curved portion **686** farthest from the housing **668** joins a

proximal end of the straight portion **688**. The junction between the curved portion **686** and the straight portion **688** of each arm **672** has a surface that can be engaged by a thumb or finger of a user of the stylet handle assembly **666**. The straight portion **688** of each arm **672** extends in a distal direction away from the junction with the curved portion **686**. The straight portion **688** extends farther in a distal direction than the housing **668**. As a result, the distal end of the straight portion **688** is disposed beyond the distal end **674** of the housing **668**. The hook portion **690** of each arm **672** extends inwardly from the distal end of the straight portion **688**.

When the latch **654** of the cover portion **642** of the hub **638** is received in the open distal end **674** of the housing **668**, the latch can slide or otherwise extend into the housing to a position in which the teeth **662** of the latch are disposed farther in a proximal direction than the hook portions **690** of the arms **672**. As the latch **654** is moved into the housing **668**, the hook portions **690** of the arms **672** engage the teeth **662** on the latch. Specifically, due to the lateral dimensions of the teeth **662**, the hook portions **690** of the arms **672** are resiliently deflected laterally outwardly by the teeth when the hook portions and the teeth initially engage one another. Continued proximal movement of the latch **654** caused the teeth **662** to reach a position that is proximally beyond the hook portions **690** of the arms **672**. At that point, the hook portions **690** resiliently snap back to their original positions and block the teeth **662** and the latch **654** from moving in a distal direction out of the housing **668**.

As will be apparent from the foregoing description, the teeth **662** of the latch **654** and the hook portions **690** of the arms **672** together form the control mechanism **664**. The control mechanism **664** controls relative movement between the stylet **678** and the first portion **619** of the wall **616**, in part, by blocking relative movement of the latch **654** and the hub **638**, on the one hand, and the housing **668** and the stylet handle assembly **666**, on the other hand, in a direction away from each other.

Relative movement of the catheter assembly **600** and the stylet handle assembly **666** toward and into engagement with one another produces lengthwise movement of the hub **638** relative to the stylet **678**, which is fixed to the handle **670** of the stylet handle assembly. The positions of the teeth **662** on the cover portion **642** of the hub **638** and the positions of the hook portions **690** of the arms **672** relative to the distal end of the housing **668** can be predetermined to permit a desired amount of relative movement between the hub **638** and the stylet handle assembly **666**. As explained below, a predetermined amount of relative movement between the hub **638** and the stylet **678** produces a predetermined amount of extension of the first portion **619** of the length of the wall **616**, a predetermined amount of reduction in the outer diameter of the first portion of the wall, and a predetermined amount of lengthwise deployment of the peripheral catheters **614**. The control mechanism **664** is thus operable to produce predetermined relative movement between the hub **638** and the stylet **678** and predetermined deployment of the peripheral catheters **614**.

As can be seen in FIG. **18**, the second orientation of the peripheral catheters **614**, in which the peripheral catheters and their associated injection port assemblies **646** are all arrayed on one side of the central catheter **612**, helps a user of the stylet handle assembly **466** to grasp and manipulate the stylet handle assembly. More particularly, having the peripheral catheters **614** and their associated injection port assemblies **646** on one side of the central catheter **612** and, therefore, on one side of the stylet handle assembly **666** permits a user of the stylet handle assembly to approach from other sides of the stylet handle assembly without having to maneuver around the peripheral catheters and injection port assemblies. Nonetheless, if desired, the peripheral catheters **614** could be maintained in their first orientation disposed in an array circumferentially around the central lumen **622** of the central catheter **612** as they are directed through the main body portion **640** of the hub **438**.

When the catheter assembly **600** is to be inserted into tissue, such as cerebral tissue, of a patient, stylet **678** is received in and engaged with the stylet handle assembly **666**. Specifically, the proximal end (not shown) of the stylet **678** is inserted into the distal end **674** of the housing **668** of the stylet handle assembly **666** and fixed in the handle **670** of the stylet handle assembly. The distal end (not shown) of the stylet **678** is inserted into and pushed lengthwise through the lumen **656** formed in the latch **654** of the cover portion **642** of the hub **638**. The distal end (not shown) of the stylet **678** is then pushed lengthwise through the main body portion **640** of the hub **638** and into the central lumen **622** of the central catheter **612**. As the distal end (not shown) of the stylet **678** approaches the distal end **624** of the central catheter **612**, the proximal end of the latch **654** of the cover portion **642** of the hub **638** of the catheter assembly **600** enters the stylet handle assembly **666** through the open distal end **674** of the housing **668** of the stylet handle assembly.

As the distal end (not shown) of the stylet **678** reaches the cap **627** adjacent the plug **626** at the distal end **624** of the central catheter **612**, the stylet is received in the open end of the cup-shaped cap, which is presented toward the central lumen **622** of the central catheter **612**. In particular, the distal end (not shown) of the stylet **678** is received in the pocket provided by the cup-shaped cap **627** so that the distal end and the pocket together help to center the stylet in the central lumen **622**. The distal end (not shown) of the stylet **678** may be rounded or may have a different shape, and the pocket provided by the cup-shaped cap **627** has a complementary shape to help center the stylet in the central lumen. When the distal end (not shown) of the stylet **678** is fully received in the cup-shaped cap **627** and contacts the closed end portion **629** of the cap, the first portion **619** of the length of the wall **616** is not yet extended, and the distal end portions **634** of the peripheral catheters **614** project from the first portion of the length of the wall, as shown in FIG. **18**.

After the distal end (not shown) of the stylet **678** contacts the closed end portion **629** of the cap **627**, the user of the stylet handle assembly **666** continues to move the handle **670** toward the hub **638**. As the latch **654** is pushed farther into the housing **668** of the stylet handle assembly **666**, the entire catheter assembly **600** is moved toward the stylet handle assembly, and the stylet **678** is pressed against the cap **627** adjacent the distal end **624** of the central catheter **612**. Pressing the stylet **678** against the closed end portion **629** of the cap **627** causes the first portion **619** of the length of the wall **616** to extend or distend axially or lengthwise into a longitudinally extended condition.

The extension or stretching of the wall **616** occurs primarily in the thickened first portion **619** of the wall because the cap **627** and the plug **626** are made of relatively inextensible material and are bonded to the inner surface **618** of the wall beyond the first portion of the wall in a distal direction. The plug **626** and the cap **627** thus effectively transfer the force applied by the stylet **678** to the wall **616** in the first portion **619** of its length. In addition, the first portion **619** of the length of the wall **616** is made of lower durometer and relatively more extensible material than the second portion **621** of the wall and thereby tends to extend or stretch in preference to the second portion of the length of the wall.

Extension or stretching of the first portion **619** of the length of the wall **616** causes the outer diameter of the wall to decrease or be reduced. This can be seen in FIGS. **20** and **21** by comparing the outer diameter of the first portion **619** in FIG. **20** with the outer diameter of the first portion in FIG. **21**. The outer diameter of the first portion **619** of the wall **616** may be reduced to any desired extent, such as less than or equal to the outer diameter of the second portion **621** of the wall. Extension or stretching of the first portion **619** of the length of the wall **616** of the central catheter **612** also causes the first portion of the wall to be drawn over the distal end portions **634** of the peripheral catheters **614** or, in effect, causes the distal end portions of the peripheral catheters to be withdrawn into the passages **630** in the wall **616**. This result occurs because the peripheral catheters **614** are adhesively bonded to surfaces (not shown) of the bushing (not shown) in the main body portion **640** of the hub **638** or are otherwise fixed against movement relative to the hub **638**.

FIGS. **20** and **21** also illustrate that extension or stretching of the first portion **619** of the length of the wall **616** does not affect the distance between distal end **624** of the central catheter **612** and the point at which each passage **630** opens onto the outer surface **620** of the wall. This distance is identified as "L**1**" in FIGS. **20** and **21**. In other words, the point at which the each passage **630** opens onto the outer surface **620** of the wall **616** remains at a substantially constant distance from the distal end **624** of the central catheter **612** during any extension or stretching of the first portion **619** of the length of the wall. The peripheral catheters **614** thus emerge from the wall **616** of the central catheter **612** at a substantially constant distance relative to the distal end **624** of the central catheter.

The durometers and thicknesses of the elastomeric materials used in the first and second portions **619** and **621** of the length of the wall **616** can be selected or tuned to provide a desired amount of reduction in the outer diameter of the first portion of the wall without excessive longitudinal extension of the first portion or use of excessive force. The durometers and thicknesses of the elastomeric materials used in the first and second portions **619** and **621** of the length of the wall **616** can also be selected or tuned to provide a desired extent to which the first portion of the wall is drawn over the distal end portions **634** of the peripheral catheters **614** without excessive longitudinal extension of the first portion. Such an extension of the first portion **619** of the wall **616** should also produce a corresponding reduction in the outer diameter of the first portion of the wall so that the outer diameter of the first portion is equal to or less than the outer diameter of the second portion **621** of the length of the wall.

As they are being covered by the wall **616** of the first portion **619** of the length of the central catheter **612** or, in effect, withdrawn into the passages **630**, the distal end portions **634** of the peripheral catheters **614** are deflected from their outwardly directed, predetermined shape and are constrained in a generally straight configuration by the wall of the central catheter. When the peripheral catheters **614** have been fully withdrawn or retracted into the wall **616** of the central catheter **612**, the outer surface **620** of the wall **616** of the central catheter appears essentially smooth and uninterrupted. The wall **616** of the central catheter **612** thus functions as a sheath portion of the central catheter and covers the distal end portions **634** of the peripheral catheters **614**.

When the stylet **678** reaches the end of its stroke, as determined by engagement or latching of the hook portions **690** of the arms **672** against the distal surfaces of the teeth **662** of the cover portion **642** of the hub **638**, the stylet is secured in place to facilitate coordinated manipulation of the stylet and the catheter assembly **600**. When the stylet handle assembly **666** is secured to the hub **638**, the stylet **678** and the catheter assembly **600** tend to move more consistently as a single unit and can be manipulated more easily and accurately. In particular, the stylet **678** can then be used to insert the extended central catheter **612** and the peripheral catheters **614** into the tissue of a patient. Because the outer diameter of the first portion **619** of the wall **616** of the central catheter **612** has been reduced due to the lengthwise extension or distension of the first portion, the opening formed in the patient's tissue is smaller than it would be otherwise. Also, because the distal end portions **634** of the peripheral catheters **614** have been withdrawn into the wall **616** of the central catheter, the peripheral catheters do not interfere with the insertion of the central catheter into the patient's tissue.

When the distal end **624** of the central catheter **612** is appropriately positioned in a patient's tissue, the hub **638** of the catheter assembly **600** is held so as to maintain the distal end of the central catheter in position. The arms **672** of the stylet handle assembly **666** can then be manipulated to disengage the hook portions **690** of the arms **672** from the teeth **662** of the cover portion **642** and to cause or permit relative movement between (a) the catheter assembly **600** and (b) the stylet handle assembly **666** and the stylet **678**. In particular, the resilience of the extended first portion **619** of the wall **616** of the central catheter **612** pulls the proximal end **628** of the central catheter in a distal direction toward the distal end **624** of the central catheter. The central catheter **612** thus returns resiliently to its initial, non-extended length, as shown in FIG. **18**.

As can be seen from the foregoing description, the control mechanism **664**, which includes the teeth **662** of the cover portion **642** and the hook portions **690** of the arms **672**, controls relative movement between the stylet **678** and the first portion **619** of the wall **616**, in part, by permitting relative movement of the hub **638** and the catheter assembly **600**, on the one hand, and the housing **668** and the stylet handle assembly **666**, on the other hand, away from each other. Although the relative movement has been described in terms of the proximal end **628** of the central catheter **612** moving in a distal direction toward the distal end **624** of the central catheter, the relative movement may involve movement of the distal end of the central catheter in a proximal direction toward the proximal end of the central catheter. In that event, the stylet **678** would be pushed by the distal end **624** of the central catheter **612** in a proximal direction, which, in turn, would push the stylet handle assembly **666** in a proximal direction away from the hub **638** of the catheter assembly **600**.

When the central catheter **612** resiliently returns to its initial, non-extended length and the wall **616** of the central catheter likewise resiliently returns from its longitudinally extended condition to its initial, non-extended length, the distal end portions **634** of the peripheral catheters **614** are no longer withdrawn into the wall **616**. The distal end portions **634** of the peripheral catheters **614** instead project from the outer surface **620** of the wall **616** of the central catheter and assume their outwardly directed, predetermined shape. As the distal end portions **634** of the peripheral catheters **614** assume their outwardly directed, predetermined shape, the peripheral catheters **614** penetrate the patient's tissue and extend into the patient's tissue away from the central catheter **612** in a radial array.

In addition, as the wall **616** of the central catheter **612** resiliently returns to its initial length, the outer diameter of the wall, particularly the first portion **619**, increases from its reduced condition back to its original dimension. The increase in the outer diameter of the wall **616** of the central catheter **612** causes the outer surface **620** of the first portion

619 of the wall 616 to press tightly against adjacent surfaces of the patient's tissue. The resulting close fit between the outer surface 620 of the wall 616 and the adjacent surfaces of the patient's tissue helps to prevent fluid introduced into the tissue by the peripheral catheters 614 from flowing back along the outer surface of the wall toward the proximal end 628 of the central catheter 612.

When the stylet handle assembly 666 is disengaged from the catheter assembly 600, the durometer of the elastomeric material in the first portion 619 of the length of the wall 616 affects the speed and force with which the central catheter 612 resiliently returns to its initial, non-extended length and the proximal end 628 of the central catheter moves in a distal direction. If, for example, the first portion 619 of the length of the wall 616 is formed of a silicone elastomer with a Shore A hardness of about 40, the first portion will return to its initial, non-extended length more quickly than if the first portion is formed of a silicone elastomer with a Shore A hardness of about 20, provided the durometer of the elastomeric material in the second portion 621 of the length of the wall 616 is the same in both instances. A quicker return of the first portion 619 to its initial, non-extended length will produce a quicker deployment of the peripheral catheters 614.

At the same time, to ensure stretching or extension of the first portion 619 of the length of the wall 616 in preference to stretching and extension of the second portion 621 of the length of the wall, a minimum difference should be maintained between the durometers of the materials from which the first and second portions are formed. With silicone elastomers having durometers measured using the Shore A scale, a minimum, it has been determined empirically that a minimum practical difference between the durometers of the materials from which the first and second portions 619 and 621 are made is about 30. This minimum desired difference between the durometers of the materials from which first and second portions 619 and 621 of the length of the wall 616 are formed may also be applied if one or both of the first and second portions is formed of a material, such as a urethane, with a durometer measured using the Shore D scale. The measured Shore D durometers may be converted to Shore A durometers, or the minimum desired difference of about 30 may be converted to, for example, a difference using the Shore D scale.

Another way of establishing the desired difference between the durometers of the materials is to view the difference as a minimum ratio between the hardnesses or durometers of the first and second portions 619 and 621 of the length of the wall 616. It has been empirically determined that a minimum practical ratio of the durometer of the material from which the first portion 619 of the length of the wall 616 is made to the durometer of the material from which the second portion 621 is made is about 1.5 to 1. A maximum practical ratio between the hardnesses or durometers of the second and first portions 621 and 619 has been determined empirically to be about 9 to 1. With elastomeric materials having durometers measured using the Shore A scale, the empirically determined maximum practical difference between the durometers of the materials from which the first and second portions 619 and 621 are made is about 80.

With the central and peripheral catheters 612 and 614 of the catheter assembly 600 appropriately positioned in the patient's tissue, therapeutic treatment of the tissue with a bioactive material can begin. To introduce the bioactive material, the threaded surface (not shown) of the connector portion 650 of each injection port assembly 646 is connected with a connector (not shown) and the distal end of a length of tubing (not shown). A proximal end (not shown) of the tubing is attached to a device (not shown), such as a pump, for delivering a fluid, such as a liquid. The fluid contains a bioactive material, such as a pharmaceutical material, and is delivered from the tubing into the central lumen 652 of the connector portion 650 of the injection port assembly 646 and then into the central lumen 632 of the associated peripheral catheter 614. The fluid flows along the central lumen 632 of the peripheral catheter 614 until it reaches the open end of the distal end portion 634 of the peripheral catheter and is thereby introduced into the patient's tissue.

If the patient's treatment is continued over an extended period of time and the catheter assembly 600 is therefore left implanted in the patient's tissue for an extended period of time, the stylet handle assembly 666 may be disengaged from the hub 638 of the catheter assembly, and the stylet may thereby be withdrawn entirely from the catheter assembly. Disengagement of the stylet handle assembly 666 and withdrawal of the stylet 678 from the catheter assembly 600 will leave open the proximal end of the lumen 656 in the cover portion 642 of the hub 638. Because the lumen 656 communicates, via the main body portion 640 of the hub 638, with the central lumen 622 of the central catheter 612, a cover (not shown) may be placed over the open proximal end of the lumen 656 to keep foreign materials from entering the proximal end 628 of the central lumen in the central catheter.

When the patient's treatment is completed, the catheter assembly 600 may be removed by pushing the stylet 678 into the catheter assembly to extend or distend the central catheter 612. If the stylet 678 has been disengaged from the catheter assembly 600, the stylet is reinserted into the lumen 656 formed in the latch 654 of the cover portion 642 of the hub 638 and pushed lengthwise through the lumen 656 toward the central catheter 612. As the stylet 678 is moved into and through the central lumen 622 of the central catheter 612, the latch 654 of the cover portion 642 of the hub 638 of the catheter assembly 600 enters the stylet handle assembly 666 through the open distal end 674 of the housing 668.

Pressing the distal end (not shown) of the stylet 678 against the cap 627 and the plug 626 adjacent the distal end 624 of the central catheter 612 as the stylet handle assembly 666 is moved closer to the hub 638 of the catheter assembly 600 causes the first portion 619 of the length of the wall 616 to extend or distend axially or lengthwise. Causing the first portion 619 of the length of the wall 616 to assume a longitudinally extended condition effectively causes the distal end portions 634 of the peripheral catheters 614 to be withdrawn into the passages 630 in the wall 616. When the peripheral catheters 614 have been fully withdrawn or retracted into the wall 616 of the central catheter 612, and the hook portions 690 of the arms 672 have engaged the distal surfaces of the teeth 662 of the latch 654, the stylet handle assembly 666 can be moved away from the patient, thereby withdrawing the catheter assembly 600 from the patient's tissue.

To enhance the convenience of using the catheter assembly 600 and, specifically, to facilitate positioning of the central catheter 612 lengthwise in a patient's tissue, the outer surface 620 of the second portion 621 of the wall 616 includes distance indicia 692 to show the distance along the second portion from the proximal end 628 of the central catheter. The distance indicia 692 may be molded into the outer surface 620 or bonded or otherwise applied to the outer surface.

Also to enhance the convenience of using the catheter assembly 600, the peripheral catheters 614 are identified at different points in the catheter assembly by reference indicia 694 and 696. In particular, reference indicia 694 are molded into or applied to an outer surface of the main body portion 640 of the hub 638 adjacent the distal end of main body

portion, which is adjacent the proximal end **628** of the central catheter **612**. At that location in the catheter assembly **600**, the peripheral catheters **614** are in their first orientation disposed in an array circumferentially around the central lumen **622** of the central catheter **612**. The reference indicia **694**, therefore, similarly appear in a circumferential array around the main body portion **640** of the hub **638** so that a different reference indicium **696** is associated with each different peripheral catheter **614**. The reference indicia **694** are the numerals "1" through "4" and are positioned adjacent corresponding peripheral catheters **614**. The reference indicia **696** are also the numerals "1" through "4" and are molded into or applied to outer surfaces of the injection port assemblies **646**. A different numeral or reference indicium **696** is associated with each different injection port assembly **646**. In each case, however, the numeral or reference indicium **696** associated with a particular peripheral catheter **614** is the same as the numeral or reference indicium **694** associated with that particular peripheral catheter.

The reference indicia **694** and **696** can be used to help identify the position of the peripheral catheters **614** relative to the central catheter **612** and, therefore, the patient's tissue. The material of which the peripheral catheters **614** are made may also be color-coded to help identify and distinguish between different peripheral catheters. Although the reference indicia **694** and **696** are shown in FIG. **18** as being numerals, they could be in any other distinguishing form, such as letters, colors, geometric shapes, or other symbols.

FIG. **22** illustrates yet another alternative configuration for the wall of the central catheter. As shown, the first portion **719** of the length of the wall **716** of a central catheter **712** has an outer surface **720** formed with raised, annular ridges **798** encircling the central catheter. The raised ridges **798** are spaced apart along the length of the first portion **719** of the length of the wall **716** of the central catheter **712**. Five raised ridges **798** are shown, but a greater or lesser number of raised ridges may be used.

Use of such raised ridges **798** can enhance sealing of the outer surface **720** of the wall **716** against the adjacent surfaces of the patient's tissue to help prevent fluid introduced into the tissue by the peripheral catheters (not shown) from flowing back along the outer surface of the wall toward the proximal end (not shown) of the central catheter. Specifically, when the wall **716** of the central catheter **712** resiliently returns to its initial length after having been extended to facilitate introduction of the central catheter into a patient's tissue, the outer diameter of the wall, particularly the first portion **719**, increases from its reduced diameter condition back to its original dimension. The increase in the outer diameter of the wall **716** of the central catheter **712** causes the outer surface **720** of the first portion **719** of the wall **716** to press tightly against adjacent surfaces of the patient's tissue. This is particularly so for the portions of the outer surface **720** that include the raised ridges **798**. The resulting close fit between the outer surface **720** of the wall **716** and the adjacent surfaces of the patient's tissue helps to prevent fluid introduced into the tissue by the peripheral catheters (not shown) from flowing back along the outer surface of the wall toward the proximal end (not shown) of the central catheter.

The peripheral catheters **614**, as well as the peripheral catheters **14**, **114**, **214**, **314**, and **414** of the embodiments of FIGS. **1-3**, **4-5**, **6-9**, **10-12**, and **13-15**, respectively, may be made of a material having a shape memory. Such a shape memory material could be used to provide the peripheral catheters **14**, **114**, **214**, **314**, **414**, and **614** with a substantially straight configuration at temperatures below a patient's normal body temperature. Such a shape memory material would provide the distal end portions **34**, **134**, **234**, **334**, **434**, and **634** of the peripheral catheters **14**, **114**, **214**, **314**, **414**, and **614** with a curved, angled, or other configuration when the peripheral catheters are exposed to a temperature at or above a patient's normal body temperature. Thus, when the catheter assemblies **10**, **100**, **200**, **300**, **400**, and **600** using such a shape memory material are introduced into a patient's tissue, the patient's body temperature would cause the distal end portions **34**, **134**, **234**, **334**, **434**, and **634** of the peripheral catheters **14**, **114**, **214**, **314**, **414**, and **614** to assume a curved, angled, or other configuration and penetrate the patient's tissue.

As previously noted, each of the catheter assemblies **10**, **100**, **200**, **300**, **400**, and **600** may have only single peripheral catheter **14**, **114**, **214**, **314**, **414**, or **614** or may have an array of multiple peripheral catheters, such as six to eight or more. Moreover, although the distal end portions **34**, **134**, **234**, **334**, and **634** of the peripheral catheters **14**, **114**, **214**, **314**, and **614**, respectively, are shown as having a predetermined curved configuration and as projecting radially outwardly from the central catheter **12**, **112**, **212**, **312**, and **612**, respectively, the distal end portions may have other predetermined configurations, such as an angled or straight configuration, and may project from the central catheter in other directions, such as ninety degrees or another angle from the central catheter or axially through the distal end **24**, **124**, **224**, **324**, and **624**, respectively, of the central catheter. The distal end portions **34**, **134**, **234**, **334**, **434**, and **634** of the peripheral catheters **14**, **114**, **214**, **314**, **414**, and **614**, respectively, may be provided with their respective predetermined configurations by, for example, heat forming either before the peripheral catheters are connected with their respective central catheter **12**, **112**, **212**, **312**, **412**, and **612** or after the peripheral catheters are connected with their respective central catheter.

If the distal end portions **34**, **134**, **434**, and **634** of the peripheral catheters **14**, **114**, **414**, and **614**, respectively, have a straight configuration and have no angle or curve with respect to the remaining portions of the peripheral catheters, the distal end portions will not be deflected by the walls **16**, **116**, **416**, and **616** of the central catheters **12**, **112**, **412**, and **612**, respectively, when the walls are extended. Likewise, if the distal end portions **234** of the peripheral catheters **214** have a straight configuration and have no angle or curve with respect to the remaining portions of the peripheral catheters, the distal end portions **234** of the peripheral catheters will not be deflected by the sheaths **292** when the wall **216** of the central catheter **212** has not yet been distended or extended sufficiently to release the sheaths.

While the central catheters **12**, **112**, **212**, **312**, **412**, and **612** and peripheral catheters **14**, **114**, **214**, **314**, **414**, and **614** have been described as being introduced into a patient's tissue and then later removed from the patient's tissue, the central and/or peripheral catheters may be fabricated of a material or materials that can be absorbed by the tissue, thereby reducing or eliminating the requirement physically to remove the catheters from the patient's tissue. Further, the peripheral catheters **14**, **114**, **214**, **314**, **414**, and **614** may be fabricated of an electrically conductive material and electrically insulated with a coating or jacket except at the tips of the distal end portions **34**, **134**, **234**, **334**, **434**, and **634**, respectively, of the peripheral catheters. The peripheral catheters **14**, **114**, **214**, **314**, **414**, and **614** could thus function as electrodes, conducting electrical signals applied to the proximal end portions of the peripheral catheters to the patient's tissue for therapeutic electrical stimulation. Finally, while the use of biocompatible adhesive materials has been described above to secure the peripheral catheters **14**, **114**, **414**, **614** to the wall **16**, **116**, **416**,

616 of the central catheter 12, 112, 412, 612 as well as to secure or attach together other components of the catheter assemblies 10, 100, 200, 300, 400, and 600, other suitable attachment or fixation mechanisms, such as radio frequency welding and molded interlocking pins or other interlocking structural features, may be used where appropriate.

It will be appreciated that the catheter assemblies 10, 100, 200, 300, 400, and 600 may be used to treat both neoplastic and non-neoplastic disorders. Bioactive materials introduced into a patient's tissue using any of the catheter assemblies 10, 100, 200, 300, 400, and 600 may include, for example, chemotherapeutic materials, viruses, proteins, radiologic materials, growth factors, peptides, and non-radioactive tracer molecules. The catheter assemblies 10, 100, 200, 300, 400, and 600 may be used in a variety of patient tissues, including, for example, brain tissue, spinal cord tissue, and tissue of any organ.

From the above description of the invention, those skilled in the art will perceive improvements, changes and modifications. Such improvements, changes, and/or modifications within the skill of the art are intended to be covered by the appended claims.

Having described the invention, the following is claimed:

1. A catheter assembly comprising:

a first catheter including a wall with an inner surface at least partially defining a lumen; and

a second catheter connected to the wall of the first catheter and disposed outward of the inner surface of the wall, the second catheter being at least partially covered by a sheath portion of the first catheter,

a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent portion of the second catheter.

2. A catheter assembly according to claim 1 wherein the durometer of the relatively high durometer elastomeric material has a minimum ratio to the durometer of the relatively low durometer elastomeric material of about 1.5 to 1.

3. A catheter assembly according to claim 1 further comprising at least a portion of a control mechanism to grasp a stylet disposed in the lumen and to control relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall.

4. A catheter assembly according to claim 3 wherein the control mechanism includes a lead screw and a nut to produce the relative movement between the stylet and the first portion of the wall, the at least a portion of the control mechanism including at least one of the lead screw and the nut.

5. A catheter assembly according to claim 3 further comprising a hub connecting a proximal end portion of the first catheter to a proximal end portion of the second catheter, the hub including the at least a portion of the control mechanism.

6. A catheter assembly according to claim 5 wherein the hub includes a first portion of a detent device, the first portion of the detent device being engageable with a second portion of the detent device to impede relative movement between the hub and the stylet.

7. A catheter assembly according to claim 1 further comprising a plurality of second catheters and a hub connecting a proximal end portion of the first catheter to a proximal end portion of each of the plurality of second catheters.

8. A catheter assembly according to claim 1 wherein the lumen communicates with an opening formed in a distal end of the first catheter, the opening being closed with an occluding material that is less extensible than the relatively low durometer elastomeric material forming the first portion of the wall, the occluding material being shaped and dimensioned to receive an end of a stylet.

9. A catheter assembly according to claim 8 wherein the occluding material is formed as a plug and is adhesively bonded to the first portion of the wall.

10. A catheter assembly according to claim 1 wherein the wall of the first catheter also has an outer surface, the outer surface of the second portion of the wall including a trough to receive the second catheter.

11. A catheter assembly according to claim 1 wherein the second catheter has a predetermined shape, the predetermined shape being provided by heat forming the second catheter before the second catheter is connected to the wall of the first catheter.

12. A catheter assembly according to claim 1 wherein the second catheter has a predetermined shape, the predetermined shape being provided by heat forming the second catheter after the second catheter is connected to the wall of the first catheter.

13. A catheter assembly according to claim 1 wherein the sheath portion of the first catheter includes the first portion of the wall of the first catheter, the first portion of the wall having an outer surface, the second catheter being at least partially disposed between the inner and outer surfaces of the wall.

14. A catheter assembly according to claim 13 wherein the lumen communicates with an opening formed in a distal end of the first catheter, the opening being closed with an occluding material that is less extensible than the relatively low durometer elastomeric material forming the first portion of the wall, the second catheter projecting out of the sheath portion of the first catheter adjacent to the occluding material.

15. A catheter assembly according to claim 1 wherein the wall of the first catheter has an outer surface, the sheath portion of the first catheter and at least a portion of the second catheter being disposed outward of the outer surface of the wall of the first catheter.

16. A catheter assembly according to claim 1 wherein the second catheter has a predetermined shape, the second catheter being deflected from the predetermined shape when covered by the sheath portion of the first catheter.

17. A catheter assembly according to claim 1 wherein the second catheter projects out of the sheath portion of the first catheter when the first portion of the wall of the first catheter is extended.

18. A catheter assembly comprising:

a first catheter including a wall with an inner surface at least partially defining a lumen extending lengthwise of the first catheter; and

a second catheter at least partially disposed in the wall of the first catheter outward of the inner surface of the wall and extending lengthwise of the first catheter,

a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent portion of the second catheter.

19. A catheter assembly according to claim 18 wherein the durometer of the relatively high durometer elastomeric material has a minimum ratio to the durometer of the relatively low durometer elastomeric material of about 1.5 to 1.

20. A catheter assembly according to claim 18 further comprising at least a portion of a control mechanism to grasp a stylet disposed in the lumen and to control relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall.

21. A catheter assembly according to claim 20 wherein the control mechanism includes a lead screw and a nut to produce the relative movement between the stylet and the first portion of the wall, the at least a portion of the control mechanism including at least one of the lead screw and the nut.

22. A catheter assembly according to claim 20 further comprising a hub connecting a proximal end portion of the first catheter to a proximal end portion of the second catheter, the hub including the at least a portion of the control mechanism.

23. A catheter assembly according to claim 22 wherein the hub includes a first portion of a detent device, the first portion of the detent device being engageable with a second portion of the detent device to impede relative movement between the hub and the stylet.

24. A catheter assembly according to claim 18 further comprising a plurality of second catheters and a hub connecting a proximal end portion of the first catheter to a proximal end portion of each of the plurality of second catheters.

25. A catheter assembly according to claim 18 wherein the lumen communicates with an opening formed in a distal end of the first catheter, the opening being closed with an occluding material that is less extensible than the relatively low durometer elastomeric material forming the first portion of the wall, the occluding material being shaped and dimensioned to receive an end of a stylet.

26. A catheter assembly according to claim 25 wherein the occluding material is formed as a plug and is adhesively bonded to the first portion of the wall.

27. A catheter assembly according to claim 18 wherein the wall of the first catheter also has an outer surface, the lumen communicating with an opening formed in a distal end of the first catheter, the opening being closed with an occluding material that is less extensible than the relatively low durometer elastomeric material forming the first portion of the wall, the second catheter projecting out of the wall through the outer surface of the first catheter adjacent to the occluding material.

28. A catheter assembly according to claim 18 wherein the wall of the first catheter also has an outer surface, the outer surface of the second portion of the wall including a trough to receive the second catheter.

29. A catheter assembly according to claim 18 wherein the second catheter has a predetermined shape, the predetermined shape being provided by heat forming the second catheter before the second catheter is connected to the wall of the first catheter.

30. A catheter assembly according to claim 18 wherein the second catheter has a predetermined shape, the predetermined shape being provided by heat forming the second catheter after the second catheter is connected to the wall of the first catheter.

31. A catheter assembly according to claim 18 wherein the second catheter has a predetermined shape, the second catheter being deflected from the predetermined shape when disposed in the wall of the first catheter.

32. A catheter assembly according to claim 18 wherein the first portion of the wall of the first catheter is longitudinally extensible, the first portion of the wall having a diameter that is reduced when the first portion of the wall is longitudinally extended, the diameter of the first portion of the wall increasing from a reduced condition when the first portion of the wall resiliently returns from a longitudinally extended condition.

33. A catheter assembly comprising:

a first catheter including a wall with an inner surface at least partially defining a first lumen; and

a second catheter including a second lumen, the second catheter being disposed outward of the inner surface of the wall, the first catheter being disposed outside of the second lumen,

a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible, the second catheter being connected to the first portion of the wall of the first catheter, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent, outwardly disposed portion of the second catheter.

34. A catheter assembly according to claim 33 wherein the durometer of the relatively high durometer elastomeric material has a minimum ratio to the durometer of the relatively low durometer elastomeric material of about 1.5 to 1.

35. A catheter assembly according to claim 33 further comprising at least a portion of a control mechanism to grasp a stylet disposed in the first lumen and to control relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall.

36. A catheter assembly according to claim 35 wherein the control mechanism includes a lead screw and a nut to produce the relative movement between the stylet and the first portion of the wall, the at least a portion of the control mechanism including at least one of the lead screw and the nut.

37. A catheter assembly according to claim 35 further comprising a hub connecting a proximal end portion of the first catheter to a proximal end portion of the second catheter, the hub including the at least a portion of the control mechanism.

38. A catheter assembly according to claim 37 wherein the hub includes a first portion of a detent device, the first portion of the detent device being engageable with a second portion of the detent device to impede relative movement between the hub and the stylet.

39. A catheter assembly according to claim 33 further comprising a plurality of second catheters and a hub connecting a proximal end portion of the first catheter to a proximal end portion of each of the plurality of second catheters.

40. A catheter assembly according to claim 33 wherein the first lumen communicates with an opening formed in a distal end of the first catheter, the opening being closed with an occluding material that is less extensible than the relatively low durometer elastomeric material forming the first portion of the wall, the occluding material being shaped and dimensioned to receive an end of a stylet.

41. A catheter assembly according to claim 40 wherein the occluding material is formed as a plug and is adhesively bonded to the first portion of the wall.

42. A catheter assembly according to claim 40 wherein the wall of the first catheter also has an outer surface, the outer surface of the second portion of the wall including a trough to receive the second catheter.

43. A catheter assembly according to claim 33 wherein the wall of the first catheter also has an outer surface, the first lumen communicating with an opening formed in a distal end of the first catheter, the opening being closed with an occluding material that is less extensible than the relatively low durometer elastomeric material forming the first portion of

the wall, the second catheter projecting out of the wall through the outer surface of the first catheter adjacent to the occluding material.

44. A catheter assembly according to claim **33** wherein the second catheter has a predetermined shape, the predetermined shape being provided by heat forming the second catheter before the second catheter is connected to the wall of the first catheter.

45. A catheter assembly according to claim **33** wherein the second catheter has a predetermined shape, the predetermined shape being provided by heat forming the second catheter after the second catheter is connected to the wall of the first catheter.

46. A catheter apparatus comprising:

a first catheter including a wall with an inner surface at least partially defining a lumen, a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible;

a second catheter connected to the wall of the first catheter and disposed outward of the inner surface of the wall, the second catheter being at least partially covered by a sheath portion of the first catheter; and

a control mechanism to engage a stylet when disposed in the lumen and to control relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall.

47. A catheter assembly according to claim **46** wherein the durometer of the relatively high durometer elastomeric material has a minimum ratio to the durometer of the relatively low durometer elastomeric material of about 1.5 to 1.

48. A catheter apparatus according to claim **46** further comprising a hub connected to a proximal end portion of the first catheter and to a proximal end portion of the second catheter, the control mechanism engaging the hub and being operable to produce controlled, relative movement between the hub and the stylet.

49. A catheter apparatus according to claim **48** wherein the control mechanism and the hub together include a lead screw and a nut to produce the relative movement between the stylet and the first portion of the wall, the control mechanism including one of the lead screw and the nut, the hub including the other of the lead screw and the nut.

50. A catheter apparatus according to claim **48** wherein the control mechanism includes a first portion of a detent device and the hub includes a second portion of the detent device, the first and second portions of the detent device being engageable with each other to impede relative movement between the hub and the stylet.

51. A catheter apparatus comprising:

a first catheter including a wall with an inner surface at least partially defining a lumen extending lengthwise of the first catheter, a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible;

a second catheter at least partially disposed in the wall of the first catheter outward of the inner surface of the wall and extending lengthwise of the first catheter; and

a control mechanism to engage a stylet when disposed in the lumen and to control relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall.

52. A catheter assembly according to claim **51** wherein the durometer of the relatively high durometer elastomeric material has a minimum ratio to the durometer of the relatively low durometer elastomeric material of about 1.5 to 1.

53. A catheter apparatus according to claim **51** further comprising a hub connected to a proximal end portion of the first catheter and to a proximal end portion of the second catheter, the control mechanism engaging the hub and being operable to produce controlled, relative movement between the hub and the stylet.

54. A catheter apparatus according to claim **53** wherein the control mechanism and the hub together include a lead screw and a nut to produce the relative movement between the stylet and the first portion of the wall, the control mechanism including one of the lead screw and the nut, the hub including the other of the lead screw and the nut.

55. A catheter apparatus according to claim **53** wherein the control mechanism includes a first portion of a detent device and the hub includes a second portion of the detent device, the first and second portions of the detent device being engageable with each other to impede relative movement between the hub and the stylet.

56. A catheter apparatus comprising:

a first catheter including a wall with an inner surface at least partially defining a first lumen, a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible;

a second catheter including a second lumen, the second lumen being disposed outside of the first lumen, the first lumen being disposed outside of the second lumen, the second catheter being connected to the first portion of the wall of the first catheter, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent, outwardly disposed portion of the second catheter; and

a control mechanism to engage a stylet when disposed in the first lumen and to control relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall.

57. A catheter assembly according to claim **56** wherein the durometer of the relatively high durometer elastomeric material has a minimum ratio to the durometer of the relatively low durometer elastomeric material of about 1.5 to 1.

58. A catheter apparatus according to claim **56** further comprising a hub connected to a proximal end portion of the first catheter and to a proximal end portion of the second catheter, the control mechanism engaging the hub and being operable to produce controlled, relative movement between the hub and the stylet.

59. A catheter apparatus according to claim **58** wherein the control mechanism and the hub together include a lead screw and a nut to produce the relative movement between the stylet and the first portion of the wall, the control mechanism including one of the lead screw and the nut, the hub including the other of the lead screw and the nut.

60. A catheter apparatus according to claim **58** wherein the control mechanism includes a first portion of a detent device and the hub includes a second portion of the detent device, the first and second portions of the detent device being engageable with each other to impede relative movement between the hub and the stylet.

61. A catheter assembly comprising:

a first catheter including a wall with an inner surface at least partially defining a lumen; and

a second catheter connected to the wall of the first catheter and disposed outward of the inner surface of the wall, the second catheter being at least partially covered by a sheath portion of the first catheter,

a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent portion of the second catheter, the relatively low durometer elastomeric material having a Shore A hardness of from about 10 to about 50, the relatively high durometer elastomeric material having a Shore A hardness of from about 80 to about 90.

62. A catheter assembly according to claim **61** further comprising at least a portion of a control mechanism to grasp a stylet disposed in the lumen and to control relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall, the control mechanism including a rack and a pinion to produce the relative movement between the stylet and the first portion of the wall, the at least a portion of the control mechanism including at least one of the rack and the pinion.

63. A catheter assembly according to claim **61** further comprising a tether secured at one end to the first portion of the wall and secured at an opposite end to another portion of the catheter assembly.

64. A catheter assembly comprising:

a first catheter including a wall with an inner surface at least partially defining a lumen;

a plurality of second catheters connected to the wall of the first catheter and disposed outward of the inner surface of the wall, the second catheters being at least partially covered by a sheath portion of the first catheter; and

a hub connecting a proximal end portion of the first catheter to a proximal end portion of each of the plurality of second catheters,

a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent portion of the second catheter,

the second catheters being disposed in a first array surrounding the first portion of the wall of the first catheter, proximal ends of the second catheters being disposed in a second array different from the first array on one side of the hub.

65. A catheter assembly comprising:

a first catheter including a wall with an inner surface at least partially defining a lumen; and

a second catheter connected to the wall of the first catheter and disposed outward of the inner surface of the wall, the second catheter being at least partially covered by a sheath portion of the first catheter,

a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent portion of the second catheter,

the lumen communicating with an opening formed in a distal end of the first catheter, the opening being closed with an occluding material that is less extensible than the relatively low durometer elastomeric material forming the first portion of the wall of the first catheter, the occluding material being shaped and dimensioned to receive an end of a stylet and being a flowable and curable material that is cured in place in the opening.

66. A catheter assembly comprising:

a first catheter including a wall with an inner surface at least partially defining a lumen extending lengthwise of the first catheter; and

a second catheter at least partially disposed in the wall of the first catheter outward of the inner surface of the wall and extending lengthwise of the first catheter,

a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent portion of the second catheter, the relatively low durometer elastomeric material having a Shore A hardness of from about 10 to about 50, the relatively high durometer elastomer having a Shore A hardness of from about 80 to about 90.

67. A catheter assembly according to claim **66** further comprising at least a portion of a control mechanism to grasp a stylet disposed in the lumen and to control relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall, the control mechanism including a rack and a pinion to produce the relative movement between the stylet and the first portion of the wall, the at least a portion of the control mechanism including at least one of the rack and the pinion.

68. A catheter assembly according to claim **66** further comprising a tether secured at one end to the first portion of the wall and secured at an opposite end to another portion of the catheter assembly.

69. A catheter assembly comprising:

a first catheter including a wall with an inner surface at least partially defining a lumen extending lengthwise of the first catheter;

a plurality of second catheters at least partially disposed in the wall of the first catheter outward of the inner surface of the wall and extending lengthwise of the first catheter; and

a hub connecting a proximal end portion of the first catheter to a proximal end portion of each of the plurality of second catheters,

a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent portion of the second catheter,

the second catheters being disposed in a first array surrounding the first portion of the wall, proximal ends of the second catheters being disposed in a second array different from the first array on one side of the hub.

70. A catheter assembly comprising:

a first catheter including a wall with an inner surface at least partially defining a lumen extending lengthwise of the first catheter; and

a second catheter at least partially disposed in the wall of the first catheter outward of the inner surface of the wall and extending lengthwise of the first catheter,

a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent portion of the second catheter,

the lumen communicating with an opening formed in a distal end of the first catheter, the opening being closed with an occluding material that is less extensible than the relatively low durometer elastomeric material forming the first portion of the wall, the occluding material being shaped and dimensioned to receive an end of a stylet and being a flowable and curable material that is cured in place in the opening.

71. A catheter assembly comprising:

a first catheter including a wall with an inner surface at least partially defining a first lumen; and

a second catheter including a second lumen, the second catheter being disposed outward of the inner surface of the wall, the first catheter being disposed outside of the second lumen,

a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible, the second catheter being connected to the first portion of the wall of the first catheter, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent, outwardly disposed portion of the second catheter, the relatively low durometer elastomeric material having a Shore A hardness of from about 10 to about 50, the relatively high durometer elastomeric material having a Shore A hardness of from about 80 to about 90.

72. A catheter assembly according to claim **71** further comprising at least a portion of a control mechanism to grasp a stylet disposed in the first lumen and to control relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall, the control mechanism including a rack and a pinion to produce the relative movement between the stylet and the first portion of the wall, the at least a portion of the control mechanism including at least one of the rack and the pinion.

73. A catheter assembly according to claim **71** further comprising a tether secured at one end to the first portion of the wall and secured at an opposite end to another portion of the catheter assembly.

74. A catheter assembly comprising:

a first catheter including a wall with an inner surface at least partially defining a first lumen;

a plurality of second catheters, each second catheter including a second lumen, each second catheter also being disposed outward of the inner surface of the wall, the first catheter being disposed outside of the second lumen; and

a hub connecting a proximal end portion of the first catheter to a proximal end portion of each of the plurality of second catheters

a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible, the second catheters being connected to the first portion of the wall of the first catheter, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent, outwardly disposed portion of a second catheter,

the second catheters being disposed in a first array surrounding the first portion of the wall, proximal ends of the second catheters being disposed in a second array different from the first array on one side of the hub.

75. A catheter assembly comprising:

a first catheter including a wall with an inner surface at least partially defining a first lumen; and

a second catheter including a second lumen, the second catheter being disposed outward of the inner surface of the wall, the first catheter being disposed outside of the second lumen,

a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible, the second catheter being connected to the first portion of the wall of the first catheter, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent, outwardly disposed portion of the second catheter,

the first lumen communicating with an opening formed in a distal end of the first catheter, the opening being closed with an occluding material that is less extensible than the relatively low durometer elastomeric material forming the first portion of the wall, the occluding material being shaped and dimensioned to receive an end of a stylet and being a flowable and curable material that is cured in place in the opening.

76. A catheter apparatus comprising:

a first catheter including a wall with an inner surface at least partially defining a lumen, a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible;

a second catheter connected to the wall of the first catheter and disposed outward of the inner surface of the wall, the second catheter being at least partially covered by a sheath portion of the first catheter; and

a control mechanism to engage a stylet when disposed in the lumen and to control relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall,

the relatively low durometer elastomeric material having a Shore A hardness of from about 10 to about 50, the relatively high durometer elastomeric material having a Shore A hardness of from about 80 to about 90.

77. A catheter apparatus according to claim **76** further comprising a hub connected to a proximal end portion of the first catheter and to a proximal end portion of the second catheter, the control mechanism engaging the hub and being operable to produce controlled, relative movement between the hub and the stylet, the control mechanism and the hub together including a rack and a pinion gear to produce the relative movement between the stylet and the first portion of the wall, the control mechanism including one of the rack and the pinion gear, the hub including the other of the rack and the pinion gear.

78. A catheter apparatus comprising:

a first catheter including a wall with an inner surface at least partially defining a lumen extending lengthwise of the first catheter, a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible;

a second catheter at least partially disposed in the wall of the first catheter outward of the inner surface of the wall and extending lengthwise of the first catheter; and

a control mechanism to engage a stylet when disposed in the lumen and to control relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall,

the relatively low durometer elastomeric material having a Shore A hardness of from about 10 to about 50, the relatively high durometer elastomeric material having a Shore A hardness of from about 80 to about 90.

79. A catheter apparatus according to claim 78 further comprising a hub connected to a proximal end portion of the first catheter and to a proximal end portion of the second catheter, the control mechanism engaging the hub and being operable to produce controlled, relative movement between the hub and the stylet, the control mechanism and the hub together including a rack and a pinion gear to produce the relative movement between the stylet and the first portion of the wall, the control mechanism including one of the rack and the pinion gear, the hub including the other of the rack and the pinion gear.

80. A catheter apparatus comprising:

a first catheter including a wall with an inner surface at least partially defining a first lumen, a first portion of the wall of the first catheter being made of a relatively low durometer elastomeric material and being relatively extensible, a second portion of the wall being formed of a relatively high durometer elastomeric material and being relatively inextensible;

a second catheter including a second lumen, the second lumen being disposed outside of the first lumen, the first lumen being disposed outside of the second lumen, the second catheter being connected to the first portion of the wall of the first catheter, extension of the first portion of the wall causing relative movement between the first portion of the wall and an adjacent, outwardly disposed portion of the second catheter; and

a control mechanism to engage a stylet when disposed in the first lumen and to control relative movement between the stylet and the first portion of the wall and consequent extension of the first portion of the wall,

the relatively low durometer elastomeric material having a Shore A hardness of from about 10 to about 50, the relatively high durometer elastomeric material having a Shore A hardness of from about 80 to about 90.

81. A catheter apparatus according to claim 80 further comprising a hub connected to a proximal end portion of the first catheter and to a proximal end portion of the second catheter, the control mechanism engaging the hub and being operable to produce controlled, relative movement between the hub and the stylet, the control mechanism and the hub together including a rack and a pinion gear to produce the relative movement between the stylet and the first portion of the wall, the control mechanism including one of the rack and the pinion gear, the hub including the other of the rack and the pinion gear.

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